UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: METFORMIN MARKETING AND SALES PRACTICES LITIGATION	Case No. 2:20-cv-2324-MCA-MAH
	Hon. Madeline Cox Arleo
This Document Relates To: *All Actions*	Hon. Michael A. Hammer

PLAINTIFFS' CONSOLIDATED MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS THE FIRST AMENDED CONSOLIDATED COMPLAINT

TABLE OF CONTENTS

PAGE(S)

TABLE OF AUTHORITIES

PAGE(S)

CASES

STATUTES

RULES

REGULATIONS

OTHER AUTHORITIES

Plaintiffs submit this Consolidated Memorandum Of Law In Opposition to the Manufacturer Defendants' Motion to Dismiss, ECF No. 132 ("Manufacturer MTD"), and the Pharmacy Defendants' Motion to Dismiss, ECF No. 133 ("Pharmacy MTD").

INTRODUCTION

This class action involves the generic medication, Metformin, which is contaminated with the dangerous carcinogen, N-nitrosodimethylamine ("NDMA"). Rather than using the same manufacturing process used by brand name manufacturers to produce Metformin, each generic Manufacturer cut corners to increase their profits at the expense of safety. As a result, the active pharmaceutical ingredient (API) produced by these Defendants became contaminated with known carcinogens, NDMA and other nitrosamines. The inherent, consistent flaws in the Defendants' manufacturing process resulted in contamination of nearly all of the Defendants' Metformin product sold in the United States.

Defendants[1] in every stage of the distribution chain had an independent duty to ensure the products they sold were the "same" as the branded drug equivalents. This duty also applies to the Defendants who sell Metformin-Containing Drugs (MCDs) (but do not manufacture them), and requires them to source their medication from reputable generic manufacturers. To be reputable, the manufacturer must adhere to the minimum, base-line manufacturing and quality assurance practices. Despite this duty, neither the Manufacturer nor Retail Pharmacy Defendants took the appropriate steps to detect contamination in their product, or prevent it from being sold to consumers. Further, this contamination was, or could have easily been, known to each Defendant based on the series of cGMP violations as repeatedly noted by the FDA.

[1] "Defendants" collectively refers to both the Manufacturer Defendants and the Retail Pharmacy Defendants, as defined in the FAC.

Because of this contamination, Metformin is inherently dangerous. As a result, this medication is adulterated, misbranded, and economically worthless. Rather than providing consumers with a drug that was the "same" as the name brand, as they are required by law, all Defendants played a role in manufacturing and distributing mislabeled, non-FDA approved contaminant to consumers all over the country. This class consists only of economic loss claims and seeks to reimburse Plaintiffs and Third Party Payors ("TPPs") for money wasted on an economically worthless, adulterated drug.

Despite all of the aforementioned facts, which were in Plaintiff's well-pleaded First Amended Consolidated Economic Loss Class Action Complaint (the "FAC"), Defendants allege that Plaintiffs lack standing and that the claims are preempted. Defendants also challenge many factual predicates. Defendants argue that Plaintiffs purportedly do not identify which MCDs and lots were used to fill each prescription; that Plaintiffs purportedly failed to properly allege which MCDs were dispensed by pharmacies, when and where purchases occurred, and so on (see Manufacturer MTD at 31). They also further insist that the FAC be dismissed because it has not been alleged that the MCDs "failed to deliver the same therapeutic benefit in treating and managing type 2 diabetes," which ignores the basis of this class action – consumers would not have knowingly purchased a medication that contains carcinogens, whether it effectively manages diabetes.

Plaintiffs are not alone in their conclusions regarding contamination. The FDA and similar regulatory bodies concluded the same thing in their own investigations that led to later recalls of MCDs. Contrary to Defendants' assertions, the FAC provides 129 pages of painstaking detail: allegations of what each Defendant did, and when, how, and why they did it. The FAC further describes how ordinary-course diligence at all distribution levels (such as the

ordinary-course diligence that did uncover the nitrosamine contamination) should have detected the contamination, or at least suspected it.

Plaintiffs need not prove each of the above details now, before fully developed discovery. Thus, Defendants' renewed arguments are not appropriate for a Rule 12(b)(6) motion, as the Court's focus should be whether or not the allegations set forth a plausible basis for relief, and whether Defendants are sufficiently on notice of those claims. The FAC meets both requirements, and amply clears the "short and plain statement" hurdle.

The rest of the Defendants' arguments for dismissal—standing, subsumption, personal jurisdiction, and preemption—are just as weak. As to standing, each Plaintiff paid money for worthless, unapproved, adulterated drugs. This is a concrete, justiciable injury traceable to the Defendants' conduct, which is all Article III requires for a plaintiff to have standing. Defendants also mistakenly argue that Plaintiffs' claims are subsumed or precluded by New Jersey and Indiana's product liability acts. But this argument only addresses a tiny subset of the states' laws pled in the FAC. Thus, the "subsumption" argument lacks merit, and certainly does not support dismissal of entire Counts.

This Court has subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d). This Court has personal jurisdiction over the non-U.S. Defendants. They have been properly served under the law and in any event Defendants misapply the rules applicable to the timing of such service. Moreover, general or specific jurisdiction exists over at least two of the non-U.S. Defendants under alter ego or agency theories, and dismissal on personal jurisdiction grounds of the claims of non-resident Class Members would be premature. Alternatively, the Court should grant jurisdictional discovery because Plaintiffs have presented facts that suggest

with reasonable particularity the possible existence of requisite contacts between these U.S. Defendants and the forum state.

Further, Plaintiffs' claims are not preempted by federal law as implied conflict or impossibility preemption does not apply. Defendants had identical obligations under federal and state law to ensure that their MCDs were the "same" as the name brand medication, and they failed to meet this obligation. Holding Defendants liable for their failures under state law does not conflict with federal law, nor do Plaintiffs' theories of recovery render simultaneous compliance impossible. There is nothing so specialized or unique here that might require this Court to abstain and refer this matter to the FDA.

For these reasons, Plaintiffs respectfully ask the Court to deny Defendants' Motions to Dismiss and state the following in support:

I. BACKGROUND

The FAC alleges an economic damages action based on Defendants' sale of Metformin-Containing Drugs ("MCDs") of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) through contamination with" nitrosamines on account of rampant and serious failures to adhere to FDA regulations regarding current Good Manufacturing Practices ("cGMPs") and state laws paralleling the same. FAC ¶ 8. The FAC brings twenty-two claims on behalf of classes of consumers to recoup the amounts that they paid for Defendants' worthless MCDs. FAC ¶¶ 77-121.

A. Facts Pleaded

1. Metformin

As explained in the FAC, Metformin is an antihyperglycemic drug used to treat and manage type 2 diabetes. FAC ¶ 2. It is widely considered to be well-tolerated and cost-effective.

Id. Metformin so essential to diabetes management that it is listed on the World Health Organization's List of Essential Medications. *Id.* ¶ 3. Metformin was first marketed in the United States in 1995, and by 2016, Metformin was the fourth-most prescribed medication in the United States and was prescribed over 81 million times. *Id.* ¶¶ 3, 4.

2. Overview Of The Generic Drug Approval Process In The United States

All branded drugs sold in the United States must first have FDA approval. To be approved, a brand drug company must submit a New Drug Application ("NDA") to the FDA that demonstrates clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355, *et seq*; *see also* FAC ¶ 111. Generic drugs, however, submit an Abbreviated New Drug Application ("ANDA"). FAC ¶ 112. ANDA applicants have a lesser burden and only have to demonstrate that their proposed drug is the generic equivalent to the brand or reference listed drug ("RLD"). *Id*. There are more than fifty (50) approved ANDAs for Metformin. FAC ¶ 125.

Generic manufacturers have an ongoing, federally imposed duty of sameness in their products, which means: the active pharmaceutical ingredient ("API") must be the same as the RLD; that the generic drug is "bioequivalent" to the RLD; and "can be expected to have the same therapeutic effect." 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iv); *see also* FAC ¶ 115. Bioequivalence is the "absence of significant difference" in the pharmacokinetic profiles of two pharmaceutical products. 21 C.F.R. § 320.1(e).

In each pharmaceutical product, there is the Active Pharmaceutical Ingredient (API) and excipient(s). The API is the part of any drug that produces the intended effects. 21 C.F.R. § 210.3(b)(7); *see also* FAC ¶ 151. Any substance other than the API that helps deliver medication is the excipient. While in certain specific instances generic manufacturers may use different excipients in the formulation of their generic drugs (provided they do not affect

bioequivalence), the API must be the same. A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. 21 U.S.C. § 355(b)(1)(A)(iii); *see also* FAC ¶ 115. In other words, a generic drug manufacturer must ensure that its generic product is the generic equivalent of the branded drug.

Before submitting an ANDA, a generic drug manufacturer may submit a Drug Master File ("DMF") to the FDA. DMFs provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of the API which make up all prescription drugs. Unlike ANDAs, DMFs are neither approved nor disapproved. Rather, the FDA simply reviews the technical contents of the DMF when the agency ultimately receives, reviews, and decides on whether to approve an ANDA.

3. Detection of Carcinogenic Contaminants

The FDA became aware that Metformin sold in other countries may contain NDMA in late 2019. Upon learning of the FDA's investigation, Valisure, an independent pharmacy, began testing the drug. Valisure is currently licensed in thirty-eight states and is accredited by the International Organization for Standardization ("ISO"). FAC ¶ 258. In response to rising concerns about counterfeit medications and reduced regulation of generics, Valisure tests every batch of every medication it dispenses. After extensively testing Metformin, on March 2, 2020, Valisure submitted a Citizen Petition to the FDA regarding detection of high levels of contamination in various generic Metformin products. FAC ¶ 260. Testing showed the medication was contaminated with a probable human carcinogen, known as N-nitrosodimethylamine (NDMA). *Id.*

4. Carcinogenicity of NDMA and other Nitrosamines

Nitrosamines are known human carcinogens. NDMA, specifically, is classified as a "probable human carcinogen" by the World Health Organization's International Agency for Research on Cancer, and is one of just sixty-six agents with this designation. FAC ¶ 254. Similarly, the Environmental Protection Agency classified NDMA as a probable human carcinogen, even with little to no human data to rely on. FAC ¶ 8 n.2. Exposure to high levels of NDMA has been linked to internal organ damage and cancer in humans. *See* FAC ¶¶ 253, 254. Anecdotally, NDMA has also been used in intentional poisonings. FAC ¶ 255. Further, according to the FDA, "Nitrosamine impurities may increase the risk of cancer if people are exposed to them at above-acceptable levels over long periods of time."[2]

The FDA has consistently and repeatedly stated that NDMA should not be present in prescription drugs, at any level. FAC ¶ 262. However, the FDA has created an interim safety limit of 96 ng per day to limit the number of drug shortages that would occur if all products contaminated with trace amounts of the carcinogen are recalled. *Id.* According to Valisure's testing results, several batches contained over ten times the daily threshold limit (determined by using a common number of pills per day). *See id.* (testing chart). NDMA, nor any other nitrosamine, is identified as an ingredient (active or inactive) or impurity in the NDA, product label, or elsewhere for any of the Defendants' MCDs. *Id.* ¶ 264.

5. Recalls

On December 5, 2019, the FDA announced that NDMA has been found in certain MCDs. FAC ¶ 272. Following the Valisure petition, the FDA conducted additional testing of Metformin, and also found levels of NDMA above the daily threshold limit in MCDs from

[2] https://www.fda.gov/news-events/press-announcements/fda-alerts-patients-and-health-care-professionals-nitrosamine-impurity-findings-certain-metformin.

various manufacturers. FAC ¶ 273. In June 2020, numerous manufacturers of Metformin recalled some, or all, of their product, including the Defendants: Amneal Pharmaceuticals, Apotex Corp., and Teva (Actavis). FAC ¶ 274. Specifically with regard to Metformin manufactured by Actavis, Valisure's testing revealed NDMA contamination levels between 180 and 345 ng per tablet, with levels reaching up to 7.6 times the FDA's daily limits (when pills are taken two to four times per day). *See id.* (testing chart). Testing results for Amneal's product was even more disturbing – detecting up to 16.5 times more NDMA than the daily threshold limit. *Id.*

According to Valisure, "the presence of NDMA in metformin products may be primarily due to contamination during manufacturing as opposed to a fundamental instability of the drug molecule." FAC ¶ 261. As alleged in the FAC, each Defendant failed to adhere to current Good Manufacturing Practices, despite having a legal duty to do so under 21 U.S.C. § 351(a)(2)(B). FAC ¶ 348. Any drug that is not manufactured in accordance with cGMP is considered "adulterated" and may not be sold or distributed in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B); *see also* FAC ¶ 142.

6. Defendants in this Litigation

a. *Manufacturer Defendants*

Defendant Actavis Pharma, Inc. ("Actavis Pharma") and Actavis, LLC ("Actavis") are wholly owned subsidiaries of Teva Pharmaceuticals. FAC ¶¶ 29-32. At all times material to this case, Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, the "Teva Defendants") and its Actavis subsidiaries engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded generic MCDs in the United States. *Id.*

Defendant Emcure Ltd. ("Emcure") is the parent company of Heritage Pharmaceuticals, Inc. ("Heritage") d/b/a Avet Pharmaceuticals, Inc. which is wholly owned by Emcure. FAC ¶ 34. In 2007, Heritage and another defendant, Granules USA, Inc. ("Granules") agreed to jointly develop, supply and market generic pharmaceutical products, including MCDs. FAC ¶ 39. Granules develops and registers products for ANDA submission, while Heritage retains the exclusive rights to those products. *Id*.

Defendant Avkare, Inc. ("Avkare") is a wholly own subsidiary of Amneal Pharmaceuticals LLC ("Amneal"). FAC ¶ 43. At all times material to this case, Amneal and Avkare (collectively, the "Amneal Entities") also engaged in the manufacturing, distribution, and sale of defective MCD's throughout the United States. *Id*. Avkare packages and relabels MCDs manufactured by Amneal. *Id*.

Defendants Aurobindo Pharma USA, Inc. ("Aurobindo USA") and Aurolife Pharma, LLC ("Aurolife") are wholly owned subsidiaries of Aurobindo Pharma, Ltd. ("Aurobindo") (collectively, the "Aurobindo Defendants"). FAC ¶¶ 45, 46. At all times material to this case, the Aurobindo Defendants engaged in the manufacturing, sale, and distribution of defective MCDs in the United States. *Id.* ¶¶ 44-46.

Defendant Ascend Laboratories, LLC is a wholly owned subsidiary of Alkem Laboratories Ltd. FAC ¶ 50. At all times material to this case, both Alkem and Ascend engaged in the manufacturing, sale, and distribution of adulterated and/or misbranded MCDs in the United States. *Id.* ¶¶ 49, 50.

b. *Retail Pharmacy Defendants*

Retail pharmacies have supply arrangements with finished dose manufacturers or wholesalers to obtain prescription drugs to dispense to consumers. Retail pharmacies stand in

direct contractual privity with consumers, because retail pharmacies (both brick-and-mortar and mail-order) are entities that dispensed drugs and received payments for Metformin from consumers. In this case, the Retail Pharmacy Defendants are CVS Health Corporation (CVS Health); Rite Aid, Walmart (including Sam's Club), and Walgreens. See FAC ¶¶ 53, 58, 66, 69, 71.

In 2011, Walgreens acquired control of Diplomat Pharmacy; therefore, "Walgreens" includes any current or former Diplomat pharmacy. FAC ¶ 56. Similarly, CVS acquired Target Corporation's pharmacies; therefore, "CVS" includes any current or former Target pharmacy. *Id.* ¶ 63. At all times material to this case, all of the Retail Pharmacy Defendants sold much of the adulterated and/or misbranded MCDs to customers in the United States and TPPS across the country. *Id.* ¶¶ 57, 65, 68, 70.

7. Defendants' Development and Sale of Contaminated Metformin API and MCDs

The pharmaceutical industry, as a whole, has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs as far back as 2005, possibly earlier. FAC ¶ 257.

a. *Teva/Actavis' Inadequate Manufacturing Processes*

Teva and its subsidiaries have long been the subject of FDA investigations due to a history of flawed and unreliable manufacturing practices, as well as consistent cGMP violations. FAC

¶ 173. In 2018, the FDA inspected an Actavis Laboratory facility, and discovered "significant violations" of cGMP regulations for finished pharmaceuticals. *Id.* ¶ 174. These violations are detailed in a Warning Letter, issued to Teva on February 1, 2019, and include (but are not limited to) failing to establish an adequate control unit with the responsibility and authority to approve or

reject all components, drug product containers, closures, in-process materials, packaging materials, labeling and drug products in violation of 21 C.F.R. § 211.22(a). *Id*. Further, the FDA found that the facility lacked "an adequate ongoing program for monitoring process controls to ensure stable manufacturing operations and consistent drug quality."[3] *Id*.

This was not Teva's first warning over manufacturing deficiencies. The Teva Defendants were warned of such deficiencies in 2013, 2016, 2017, and a separate account in 2018, which demonstrates "that executive management oversight and control over the manufacture of drugs is inadequate."[4] FAC ¶ 176. The Teva Defendants' failure to establish and monitor manufacturing processes "may be responsible for causing variability in the characteristics of in-process material and the drug product"; and not cleaning equipment and utensils at appropriate intervals "to prevent malfunctions that would alter the safety, identity, strength, quality or purity of the drug product."[5] *Id.* ¶ 175. As discussed in the FAC, the Defendants' facilities were repeatedly inspected and criticized by the FDA for failing to adhere to basic manufacturing requirements, specifically with regards to cleaning protocols. *See id.* ¶¶ 176-81. Failure to maintain a clean facility and clean equipment multiplies the likelihood of contamination during the manufacturing process, which is precisely what occurred. Because of the Teva Defendants' failure to remedy the litany of violations it received from the FDA, they willfully and recklessly introduced contaminated, adulterated and/or misbranded metformin containing products into the U.S. market. *Id.* ¶ 182.

---

[3] FDA, *Actavis Laboratories FL, Inc.,* (Feb. 1, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/actavis-laboratories-fl-inc-567857-02012019.

[4] FDA Form 483, *Actavis Laboratories FL, Inc.*, (July 19, 2018).

[5] *Id.*

b. *Emcure/Granules/Heritage's Inadequate Manufacturing Processes*

The Emcure/Granules/Heritage Defendants engaged in similar cGMP violations. Emcure has been inspected 12 times since 2009, and has received numerous warning letters and forceful criticisms from the FDA. FAC ¶¶ 188-205. The FDA reprimanded Emcure for failing to "adequately investigate" failures in sterility, and failed to investigate the root cause of bacterial growth in their drug products;[6] as well as failing to "validate or verify all analytical methods" to be used for the "release of raw materials" for use in manufacturing. *Id.* ¶¶ 189-90. These Defendants have been cited for failing to report adverse events, only conducting visual inspections of its API (as opposed to testing API upon receipt); and making changes to its API manufacturing process without justification, among other things. *Id.* ¶¶ 192, 191, 197.

The FDA has consistently reported that Heritage's laboratory controls lacked the appropriate specifications and test procedures to assure that drug products conform to the appropriate standards of identity, strength, quality and purity. *Id.* ¶¶ 199. Further, it lacked control procedures to monitor the manufacturing process, and failed to document any monitoring and control methods from its process equipment. *Id.* ¶¶ 201. The electronic data Heritage did have was not adequately controlled to prevent alteration. *Id.* ¶¶ 202.

c. *Amneal/Ankare's Inadequate Manufacturing Processes*

Amneal and AvKare also have a long history with the FDA. Amneal's first problematic manufacturing processes were noted by the FDA as early as 2003. FAC ¶ 208. Amneal's facilities were inspected 94 times from 2003 to present. *Id.* ¶ 209. This Defendant has been cited by the FDA for numerous violations, including, but not limited to, failing to review (or

[6] https://www.fda.gov/inspections-compliance-enforcement-and-criminalinvestigations/warning-letters/emcure-pharmaceuticals-limited-576961-08022019.

even requesting to review) raw data from testing by third-party vendors; failing to appropriately create or maintain written records of investigations into unexplained discrepancies; and failing to test materials received from other suppliers. *Id.* ¶ 211-13.

d. *Aurobindo's Inadequate Manufacturing Processes*

Aurobindo and its subsidiaries have been the subject of numerous and extensive FDA investigations, which revealed its seriously flawed and unreliable manufacturing processes, as well as a history of recurring cGMP violations. In 2016, the FDA inspected an Aurobindo facility and found that Aurobindo's investigations were inadequate. FAC ¶ 218. The FDA discovered that Aurobindo failed to initiate stability testing or track stability deviations and also noted that this was "a repeat observation from the 2014 inspection." *Id*. Just a few months later, the FDA returned, only to find a new list of violations, including Aurobindo's failure to create a written procedure for ensuring "that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." *Id.* ¶ 219.

The next year, the FDA found that Aurobindo inadequately validated equipment cleaning procedures, and that changes to written procedures are not drafted, reviewed, and approved by the appropriate organizational unit, among other things. *Id.* ¶¶ 220-221. Four months later, the FDA reiterated that "[t]here are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess," adding that "[c]ontrol procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product." *Id.* ¶ 222. Similar violations were detected and reiterated by the FDA for years, and Aurobindo made no

effort to correct any of these errors. Instead, it continued to engage in inadequate manufacturing processes that led to the contamination of its MCDs. *See id.* ¶¶ 223-228.

e. *Alkem/Ascend's Inadequate Manufacturing Processes*

Like the rest of the Defendants, Alkem and Ascend have a long list of cGMP violations. In September 2016, the FDA found that Alkem was grossly deficient in ensuring the stability of its drug products, specifically that Alkem's "[l]aboratory records do not include complete data derived from all tests, examinations and assay necessary to ensure compliance with established specifications and standards." FAC ¶ 231. Specifically, the FDA found that the quality control unit did not report all test results from out-of-specification ("OOS") investigations. *Id.* The FDA also found that Alkem re-tested OOS results, and violated production control procedures in under unjustifiable circumstances. *Id.* ¶¶ 231, 233.

The FDA also found that Alkem's quality control unit was essentially non-existent, as it had not established an effective system, even the most basic system, for managing the quality of its drug products. *Id.* ¶¶ 235-236. According to the FDA, there were "no written procedures for production and process controls designed to assure drug products the identity, strength, quality and purity they purport or are represented to possess." *Id.* ¶ 238. Alkem did not have full audit programs for sampling drug products, which prevented "meaningful review of the [sampling] instrument history" (i.e., to detect the manipulation or deletion of sampling data). FAC ¶ 239. In March 2018, after inspecting yet another Alkem facility, the FDA reported, "[t]here is no quality control unit," adding in all caps, "***THIS IS A REPEAT OBSERVATION***". *Id.* ¶ 241. The FDA found similar continuous violations at each of Alkem's facilities up until 2020. *Id.* ¶¶ 243-247.

8. Defendants Knew or Should have known about the Nitrosamine in their Metformin API and MCDs.

Each Defendant had actual or constructive notice of nitrosamine contamination in their MCDs, but failed to sequester the contaminated product or to ensure they did not sell contaminated MCDs to consumers. *See* FAC ¶¶ 263-271. Moreover, none of Defendants' MCDs identify NDMA, NDEA, or other nitrosamines as an ingredient on the products' labels or elsewhere. FAC ¶ 264. This is because these nitrosamines are probable human carcinogens, and are not approved to be included in Metformin API. Inclusion of nitrosamines in Defendants' MCDs renders the drug adulterated and misbranded compared to Defendants' warranties and representations, and thus, the drug is economically worthless. *Id.* ¶ 8.

LEGAL STANDARD

Defendants' motions under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) are a purported facial attack on Plaintiffs' standing. *See* Manufacturer MTD at 12. A facial attack is an argument that considers a claim on its face and receives the same standard as a Rule 12(b)(6) motion. *See Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014). Although on a motion to dismiss for lack of standing the plaintiff must establish the elements of standing, "with the manner and degree required at the successive stages of litigation," general factual allegations of injury caused by the defendant's conduct will suffice. *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007) (quotations omitted). A court reviewing a facial attack may consider only the allegations of the complaints—and must do so in the light most favorable to the plaintiff. *Id.* (quoting *In re Schering Plough Corp.*, 578 F.3d 235, 243 (3d Cir. 2012)).

To survive a 12(b)(6) motion to dismiss, the plaintiff needs to allege only "sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570

(2007)). Plausible factual allegations "raise a right of relief above the speculative level." *Twombly*, 550 U.S. at 555. Stated otherwise, "[a] plaintiff need only put forth allegations that raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Thompson v. Real Estate Mortg. Network*, 748 F.3d 142, 147 (3d Cir. 2014) (internal quotations and citation omitted). Accordingly, the only issue before the Court is whether the plaintiff is "entitled to offer evidence to support the claims." *Oatway v. Am. Int'l Grp., Inc.*, 325 F.3d 184, 187 (3d Cir. 2003).

ARGUMENT

I. PLAINTIFFS ADEQUATELY PLEAD STANDING

Plaintiffs have standing to bring the claims in the FAC. Article III standing is satisfied if a plaintiff shows: (1) an injury in fact; (2) a causal connection between the injury and the conduct that is fairly traceable to the challenged action of the defendant; and (3) it is likely to be redressed by a favorable decision. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). Defendants challenge only the first two elements.

To determine whether the elements of standing are met, courts "separate [the] standing inquiry from any assessment of the merits of the plaintiff's claim," by assuming "that a plaintiff has stated valid legal claims." *Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017). "[G]eneral factual allegations of injury resulting from the defendant's conduct may suffice" because courts "presume that general allegations embrace those specific facts that are necessary to support the claim." *Lujan*, 504 U.S. at 561 (quotations omitted). It is only in the summary judgment phase—after discovery—that a plaintiff must support the allegations with evidence of specific facts. *Id.* Thus, Defendants' contention that Plaintiffs must allege any more tracing allegations than those alleged in the FAC is baseless. *See* Manufacturer MTD at 16. In the

context of a class action, Article III standing need only be satisfied by at least one named plaintiff. *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 359 (3d Cir. 2015) (quoting *McNair v. Synapse Grp. Inc.*, 672 F.3d 213, 223 (3d Cir. 2012)).

A. Plaintiffs Suffered An Injury Because Of Defendants' Failure To Comply With FDA Standards

"The injury-in-fact element is not Mount Everest. The contours of the injury-in-fact requirement … are very generous, requiring only that claimant allege some specific, identifiable trifle of injury." *In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633-34 (3d Cir. 2017) (quoting *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 278 (3d Cir. 2014)). Injury in fact has three components: (1) a plaintiff must have suffered an invasion of a legally protected interest; (2) the injury to plaintiff must be particularized and concrete; (3) the injury must have been actual or imminent. *Mileo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 478 (3d Cir. 2018). Defendants challenge only the second and third components.

Defendants argue that Plaintiffs' injury is purportedly hypothetical because Plaintiffs "allege no physical injury" associated with ingesting contaminated MCDs or that the contaminated MCDs were "ineffective or less effective therapeutically." Manufacturer MTD at 17. Putting aside Defendants' implicit suggestion that MCDs contaminated with cancer-causing NDMA are just as safe as those without NDMA, the argument overlooks the fact that each plaintiff suffered a monetary loss by purchasing adulterated MCDs, which Congress has found to be unsafe for consumption and thus economically worthless. *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 926 (11th Cir. Oct. 28, 2020) (en banc) ("Although the plaintiffs suffered no physical harm from the supplement, we concluded that they were sold a worthless product 'that Congress judged insufficiently safe for human ingestion.'") (quoting *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019)); *Muransky*, 979 F.3d at 927 ("Even

without any direct harm, a plaintiff can establish an injury in fact by showing that a statutory violation created a risk of real harm.") (internal quotations omitted). Defendants' argument should be rejected.

"Typically, a plaintiff's allegations of financial harm will easily satisfy each of these components." *Cottrell v. Alcon Labs.*, 874 F.3d 154, 163 (3d Cir. 2017). "Monetary harm is a classic form of injury-in-fact. Indeed, it is often assumed without discussion." *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 293 (3d Cir. 2005) (citation omitted). *See also Nat. Res. Def. Council, Inc. v. U.S. Food and Drug Admin.*, 710 F.3d 71, 85 (2d Cir. 2013) ("Even a small financial loss is an injury for purposes of Article III standing."). All a plaintiff needs to allege is "sufficient factual allegations that, if proven true, would permit a factfinder to determine that she suffered at least *some* economic injury." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices and Liab. Litig.*, 903 F.3d 278, 287 (3d Cir. 2018) (emphasis in original); *see also Carter v. HealthPort Techns., LLC*, 822 F.3d 47, 55 (2d Cir. 2016) ("Any monetary loss suffered by the plaintiff satisfies [the injury in fact] element; even a small financial loss suffices.") (internal quotations omitted)).

Being defrauded or paying for a valueless product in a quintessential injury in fact. *See Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 361 (3d Cir. 2013). In *Debernardis*, 942 F.3d at 1084-88, plaintiffs purchased supplements that were defective, adulterated, and therefore worthless. The court held that the consumer plaintiffs had sufficiently alleged standing:

> [W]e accept, at least at the motion to dismiss stage, that a dietary supplement that is deemed adulterated and cannot lawfully be sold has no value. Through the FDCA, as amended by the DSHEA, Congress banned the sale of adulterated dietary supplements because of its concern that such substances could not safely be ingested. See 21 U.S.C. §§ 331(a), 342(f)(1)(B), 393(b)(2). A person who purchased an adulterated dietary supplement thus received a product that Congress judged insufficiently safe for human ingestion. Given Congress's judgment, we conclude that the purchaser of such a supplement received a

> defective product that had no value. This conclusion is consistent with the well-established benefit-of-the-bargain theory of contract damages, which recognizes that some defects so fundamentally affect the intended use of a product as to render it valueless.

Id. at 1085. Relying on Congress's judgment that adulterated dietary supplements have no legal value, the court found that consumers who purchased those products had alleged economic injuries sufficient to confer standing. *Id.* at 1086 ("[P]laintiffs have standing because they allegedly experienced an economic loss when they purchased a product that the FDCA banned from sale because it was presumptively unsafe").[7]

Here, Plaintiffs suffered an injury because they paid for a worthless product. FAC ¶ 277 ("The recalled MCDs are worthless and were illegally distributed and sold to consumers and reimbursed by TPPs, causing economic loss to consumers and TPPs."). Like the adulterated substances in *Debernardis*, Defendants' MCDs were adulterated and it was illegal for the Defendants to sell them. *See*, *e.g*., FAC ¶¶ 285–290. Plaintiffs each paid for one or more or more of Defendants' MCDs. *Id.* ¶¶ 12–18. Like the decisions cited above, Plaintiffs' monetary

[7] The Eleventh Circuit subsequently reaffirmed *Debernardis* in *Muransky*, 979 F.3d at 927. Other courts have reached similar conclusions. *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47, 48 (9th Cir. 2018) (finding that a consumer who purchased skin lotion product that was unapproved, but should have been subject to pre-market approval as a "drug" under FDCA, had sufficiently alleged economic injury standing by purchasing a product that "should not have been sold" because it was illegal to sell the product); *In re Aqua Dots Prods. Liability Litig.*, 654 F.3d 748, 751 (7th Cir. 2011) (finding consumers who purchased recalled water beads children's toys had sufficiently alleged standing where "[t]he plaintiffs' loss is financial: they paid more for the toys than they would have, had they known of the risks the beads posed to children. A financial injury creates standing."); *Yachera v. Westminster Pharmaceuticals, LLC*, 477 F. Supp. 3d. 1251, 1264 (M.D. Fla. 2020) (finding consumers who purchased adulterated thyroid tablets had alleged standing and that "the absence of allegations that a medication made a plaintiff sick or failed to work as intended is not fatal to establishing injury in fact where, as here, each plaintiff plausibly pleads that she would not have purchased the medication had she known it was defective."); *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline, LLC*, 2016 WL 6612804, at *6-7 (E.D. Pa. Nov. 9, 2016) ("Considering the facts alleged bearing on Plaintiffs' economic injury—the cGMP violations, quality of drug issues, FDA seizure of stocks of adulterated drugs . . . Plaintiffs have sufficiently pleaded they suffered injury to their businesses as a result of paying for the adulterated at-issue drugs."); *Hope Med. Enter. v. Fagron Compounding Servs., LLC,* 2020 WL 3803029, at *17 (C.D. Cal. July 7, 2020) (citing *Debernardis* and agreeing with plaintiff's argument that "because defendants[] cannot legally sell their drugs, consumers are necessarily injured by buying an illegal product").

harm is based on the fact that the MCDs were contaminated with NDMA, manufactured in flagrant disregard of cGMPs, unsuitable for consumption, and adulterated, misbranded and unapproved and illegally introduced into the United States. Under these circumstances, Plaintiffs would not (and indeed, could not) have bought the MCDs on the same terms had they been aware of these facts. *Id*. Plaintiffs have thus sufficiently alleged facts that give rise to an inference of harm, which is all that is required at this stage in the proceedings. *See Thompson*, 748 F.3d at 147.

If a plaintiff alleges that the purchase of a product provided her with an economic benefit that is worth less than the economic benefit for which plaintiff bargained, plaintiff would have sufficiently established an economic injury. Defendants' reliance on *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices and Liab. Litig.*, 903 F.3d at 290, is misplaced. There, the Third Circuit held that the plaintiff failed to show standing because the plaintiff pled buyer's remorse, failed to plead that a product she purchased was worth even a penny less than what she paid, and failed to plead that the product put her at risk of developing cancer. *Id.* at 288-90. The plaintiff also argued that she did not have to offer any economic theory of injury at the pleading stage. *Id.* at 287.

Unlike the plaintiff in *In re Johnson & Johnson*, Plaintiffs here have alleged facts that show that they purchased MCDs based on Defendants' representations and material omissions and assurances of quality control and purity. *See*, *e.g.*, FAC ¶¶ 12-18, 82. Plaintiffs also plead, unlike the plaintiff in *In re Johnson & Johnson*, that Defendants' MCDs are economically worthless. *Compare* FAC ¶¶ 6, 262-63, 275 (pleading that Defendants' MCDs are worthless), *with In re Johnson & Johnson*, 903 F.3d at 288 (noting that plaintiff did not allege that the baby powder product was worth less than what she paid). Plaintiffs' allegations are bolstered by the

Manufacturer Defendants' recall of their MCDs, while Johnson & Johnson continued to sell its baby powder product while the lawsuit was pending. Indeed, Judge Kugler recently distinguished *In re Johnson & Johnson* from nearly identical facts to those alleged here:

> In *Johnson*, the plaintiff failed to satisfy this minimal requirement because she did not provide sufficient facts which would allow a factfinder to determine that she suffered an economic injury from purchasing improperly labeled Baby Powder. Put differently, she did not explain how purchasing improperly labeled baby powder caused her an economic injury other than merely calling it that. Here, Plaintiffs have explained how purchasing the VCDs caused them to suffer an economic injury by presenting a concrete theory of economic loss—the VCDs were worthless or had no market value because contrary to Defendants' representations, they were adulterated, misbranded, non cGMP compliant, and illegal to sell.

In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig., 2021 WL 100204, at *9 (D.N.J. Jan. 12, 2021) ("*In re Valsartan II*"); *see also id.*, at *10 (noting the plaintiff in *Johnson* "made three fatal mistakes" that were not present in *In re Valsartan II*).

The recent *Thorne v. Pep Boys Manny Moe & Jack Inc.*, 980 F.3d 979 (3d Cir. 2020) decision is similarly distinguishable. In *Thorne*, the plaintiff did not allege the tires she purchased were defective in any way and they had not been recalled. *Thorne,* 980 F.3d at 884-85 ("She did not allege any performance problems, physical defects, or recall associated with her tires."). Thus, Plaintiffs have standing.

1. <u>Defendants Promised A Generic Equivalent Drug But Delivered An Illegal Non-Equivalent Product Instead</u>

Even if the purchase of contaminated MCDs was not sufficient to allege injury in fact (and it is), Plaintiffs have still alleged concrete injuries because the MCDs that they purchased were not equivalent to the drugs' respective RLD. An injury based on a benefit-of-the-bargain theory depends on the nature of the bargain itself. *See, e.g.*, *McDonough v. Bayer Healthcare, LLC*, 2011 WL 2119107, at *4 (D.N.J. May 26, 2011) (Martini, J.) (analyzing whether defendants' promises regarding the quality of a pesticide and its impact on animals formed the

basis of the bargain to constitute an express warranty); *In re Ford Motor Co. E-350 Prods. Liab. Litig.*, 2008 WL 4126264, at *4-5 (D.N.J. Sep. 2, 2008) (Ackerman, J.) (examining nature of the bargain and plaintiffs' reliance thereon before looking to the existence of warranty and benefit of the bargain analysis).

Plaintiffs purchased Defendants' MCDs based on Defendants' representations and warranties that their MCDs were bioequivalent to their RLD, and that they were non-adulterated (that is, non-contaminated and originating from cGMP compliant manufacturing facilities or processes). *See*, *e.g.*, FAC ¶¶ 146-54, 264-321 (discussing assurances made by Defendants that their MCDs were compliant with cGMPs and equivalent to RLDs). The value of Defendants' generic product is entirely dependent on it being an FDA-approved therapeutic equivalent (*i.e.*, the *same* as the RLD). But Defendants omitted material information that these representations were false, and that their products were not the generic equivalent, and neither pure, unadulterated, nor cGMP compliant. These omissions induced Plaintiffs' actions and reliance at purchase, and harmed Plaintiffs because the MCDs were worthless. *See id.* ¶¶ 130-45, 404, 420, 446.

Courts in this District that have considered the Plaintiffs' proposed benefit-of-the-bargain theory have found such allegations sufficient to establish injury-in-fact. In *In re Valsartan II*, defendants manufactured and distributed adulterated drugs that led to an FDA recall of those drugs. *In re Valsartan II*, 2021 WL 100204, at *4. Judge Kugler held that plaintiffs had standing because (1) plaintiffs received a worthless product thus failing to receive the benefit of their bargain and (2) plaintiffs suffered an economic loss when they had to purchase replacement medication due to the FDA recall. *Id.*, at *9 ("[Plaintiffs] allege the economic benefit they received from Defendants' VCDs was worth less than the economic benefit for which they

bargained because the VCDs were contrary to Defendants' representations and warranties. More precisely, Plaintiffs allege Defendants' VCDs were 'worthless' because they bargained for a pure, unadulterated, properly branded, and cGMP compliant generic drug but received an impure, adulterated, misbranded, non cGMP compliant, and illegal generic drug. These allegations … are sufficient for a factfinder to determine the Plaintiffs suffered at least some economic injury because they show Plaintiffs received a less valuable product."); *see also id.*, at *10 ("[T]he third theory of economic injury, the difference between the cost of the VCDs and the replacement drugs, does suffice to confer standing.").

Plaintiffs failed to receive the benefit of their bargain. Defendants sold to Plaintiffs illegal adulterated drugs that Defendants were forced to recall. FAC ¶¶ 272-278. Once the FDA forced the Manufacturer Defendants to recall their illegal adulterated MCDs, consumers had to obtain a prescription for a safe alternative drug and paid a replacement price. *Id.* ¶ 278. Thus, regardless of any purported efficacy of Manufacturer Defendants' MCDs, Plaintiffs received a valueless product that ultimately had to be replaced by a safe alternative.

In *Blue Cross Blue Shield*, third-party payor plaintiffs sought damages because they purchased a drug that defendants warranted as compliant with cGMPs. *See Blue Cross Blue Shield Assoc. v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 537 (E.D. Pa. 2019). Instead, plaintiffs received drugs from manufacturing plants forced to issue recalls by the FDA due to Glaxo's cGMP failures. *Id.* Glaxo (like the Defendants here) argued that the cGMP violations did not impact the drug itself, but the court rejected that argument. Failure to comply with cGMPs gives rise to a plausible inference that the products at issue are worthless to third-party payors ("TPPs") (and consumers), and that such an injury was sufficient to confer standing. *Id.* at 554-55.

The foregoing applies equally both to consumer class members and TPP class members. *See*, *e.g.*, *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516, 531 (3d Cir. 2004) (TPP has standing to sue drug manufacturer for their misrepresentations when it results in the insurance company's payment of inflated drug prices); *Blue Cross Blue Shield*, 417 F. Supp. 3d at 565 (TPPs had standing to sue manufacturer for cGMP violations); *American Fed'n of State Cty. & Mun. Employees v. Ortho-McNeil-Janssen Pharm., Inc.*, 2010 WL 891150, at *3 (E.D. Pa. Mar. 11, 2010) (TPPs adequately alleged injury in fact for the costs they have paid or will pay to replace defective prescription Fentanyl patches)*; In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 543 (D.N.J. 2004) (Greenaway, J.) (holding that third-party payors suffered an injury-in-fact for standing purposes). In fact, the Court's prior order on Defendants' motion to dismiss found that Plaintiff MSP Recovery Claims, Series LLC's "adequately alleged that it suffered an injury, as it contends that it was assigned the rights of certain TPPs who made payments for the Manufacturer Defendants' MCDs contaminated with NDMA." ECF No. 124 at 3 n.4.

Accordingly, Plaintiffs have plausibly alleged an injury in fact based on the false bioequivalence or "sameness" of their MCDs.

2. Plaintiff's Injuries Are Fairly Traceable to Defendants' Conduct

In the FAC, Plaintiffs have cured the deficiency the Court was concerned with in finding causation and have traced each Defendants' conduct to an injury suffered by a Plaintiff.

Defendants argue that although the FAC details which Manufacturer Defendant sold the MCD, and from which Pharmacy Defendant each Plaintiff purchased the MCD, Plaintiffs have not connected Defendants' actions to at least one injured Plaintiff. Manufacturer MTD at 19; *see also* Pharmacy MTD at 7 (arguing that Plaintiffs' injuries cannot be traced to it because the Complaint purportedly did not allege that Plaintiffs obtained MCDs from a specific Retail

Pharmacy Defendant). Defendants' argument ignores the procedural posture of this case and requires Plaintiffs to plead specificity without the benefit of any discovery. Even so, the argument is meritless.

Taking the allegations as true, Plaintiffs' injuries are fairly traceable to the Defendants' conduct. "[T]he traceability prong focuses on *who* inflicted [] harm." *In re Mercedes-Benz Emissions Litig.*, 2016 WL 7106020, at *6 (D.N.J. 2016) (emphasis in original) (citing *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 142 (3d Cir. 2009)). To satisfy traceability, Plaintiffs need only "allege sufficient facts to plausibly support 'a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant and not the result of the independent action of some third party not before the court.'" *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 247 (3d Cir. 2012) (quoting *Lujan*, 504 U.S. at 560). Causal connection is not an onerous standard. *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 55 (2d Cir. 2016).

This causal connection is less than proximate causation needed to succeed on the merits of a tort claim. *See Pub. Interest Research Group of N.J., Inc. v. Powell Duffryn Terminals Inc.,* 913 F.2d 64, 72 (3d Cir. 1990). Even an "indirect causal relationship will suffice." *Pitt News v. Fisher,* 215 F.3d 354, 361 n.4 (3d Cir. 2000); *accord Toll Bros. v. Twp. of Readington*, 555 F.3d 131, 142 (3d Cir. 2009); *Carter*, 822 F.3d at 55-56 ("A defendant's conduct that injures a plaintiff but does so only indirectly, after intervening conduct by another person, may suffice for Article III standing.").

Here, the Court identified two issues with the traceability in the original Consolidated Complaint: "no Consumer Plaintiff alleges (1) which Manufacturer Defendant's drugs they purchased, or (2) at which Pharmacy Defendant they purchased their drugs. ECF No. 124, at 4.

Contrary to Defendants' argument, the FAC does not tactically lump together Defendants. Manufacturer MTD at 20. Instead, the FAC identifies the specific Manufacturer Defendant that sold, manufactured, and/or distributed the MCD that Plaintiff ultimately purchased. FAC ¶¶ 12-18. The FAC further details which Plaintiff purchased an MCD, the Pharmacy Defendant from which the Plaintiff purchased the MCD, and the Manufacturer Defendant that sold the MCD to the Defendant Pharmacy. *Id.* Those MCDs that Plaintiffs ultimately purchased were illegal adulterated and misbranded drugs—not the promised bioequivalent Metformin. *Id.* at ¶¶ 150–58.

The Manufacturer Defendants' quality assurances and cGMP compliance representations, as well as the Pharmacy Defendants' promises that they were selling merchantable, non-misleading, and quality products, induced Plaintiffs' MCD purchases. FAC ¶ 27. As such Pharmacy Defendants "sold a large portion of the adulterated and/or misbranded MCDs to U.S. consumers and TPPs during the class period." FAC ¶¶ 57, 65, 68, 70. Thus, Plaintiffs adequately pled involvement by Pharmacy Defendants.[8] Plaintiffs have also plead sufficient facts that they expected and bargained for Defendants' assured quality control and product purity, establishing a link between Plaintiffs' injuries and Defendants' conduct. These allegations are enough to establish traceability. *See*, *e.g.*, *Carlough v. Amchem Prods., Inc.*, 834 F. Supp. 1437, 1455 (E.D. Pa. 1993) (finding traceability prong met).

Accordingly, Plaintiffs have adequately alleged in the FAC (1) which Manufacturer Defendant's drug they purchased and (2) at which Pharmacy Defendant they purchased their

[8] Contrary to CVS's assertion, Plaintiffs' theory of liability against CVS and other pharmacy defendants is not some market share theory of liability. Plaintiffs pleaded that CVS and other pharmacy defendants, "dispensed and received payment for the adulterated and/or misbranded MCDs for which consumers paid and TPPs reimbursed." FAC ¶ 51. CVS and the other Pharmacy Defendants are liable because they had a duty to ensure that the MCDs they sold were merchantable, non-misleading, and of represented quality. Plaintiffs' allegations must be taken as true at the motion to dismiss stage.

drugs, which is all this Court further required to find traceability of the Plaintiff's injuries (paying for a valueless product). *See* ECF No. 124 at 4.

B. Named Plaintiffs May Assert Claims On Behalf Of Out-Of-State Putative Class Members In Other States

Defendants argue that Plaintiffs lack standing to assert claims on behalf of putative class members in jurisdictions where Plaintiffs do not reside. Defendants' argument is meritless. The Third Circuit has held that so long as the named plaintiff in a class action can establish standing, putative class members need not establish Article III standing. *Neale, LLC*, 794 F.3d at 362 ("We now squarely hold that unnamed, putative class members need not establish Article III standing. Instead, the 'cases or controversies' requirement is satisfied so long as a class representative has standing, whether in the context of a settlement or litigation class.").

The Third Circuit has further instructed that Rule 23 certification issues, such as adequacy, should not be prematurely embedded into the Article III standing analysis. In *Mielo v. Steak n' Shake Operations, Inc.*, 897 F.3d 467 (3d Cir. 2018), the Third Circuit rejected the argument that named plaintiffs did not have standing to sue on behalf of putative class members who experienced alleged ADA violations in defendant's restaurant branches outside the forum state. *Id*. at 479. Courts in this Circuit also have considered and adopted the Second Circuit's reasoning in *Langan*, which held that "whether a plaintiff can bring a class action under the state laws of multiple states is a question of predominance under Rule 23(b)(3), not a question of standing under Article III." *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 897 F.3d 88, 96 (2d Cir. 2018).

Judge Shipp's holding in *Rolland*, which applies the *Langan* analysis, is also on point. In *Rolland*, defendants made the identical argument that class representatives lacked standing to bring nationwide class claims under various states' laws on behalf of putative out-of-state class

members. *Rolland v. Spark Energy LLC*, 2019 WL 1903990, at *5 n.6 (D.N.J. Apr. 29, 2019). Judge Shipp rejected the argument as "unpersuasive." *Id.* (denying motion to dismiss). Other courts in the Third Circuit have ruled similarly. *See*, *e.g.*, *Rickman v. BMW of N. Am.*, 2020 WL 3468250, at *11 (D.N.J. June 25, 2020) (McNulty, J.) (declining to address whether named plaintiff has standing to assert claims in under various state laws because the "more prudent approach would be to defer consideration of this argument until the certification stage"); *Gress v. Freedom Mortg. Corp.*, 386 F. Supp. 3d 455, 462 (M.D. Pa. 2019) (denying motion to dismiss because "Plaintiffs' capacity to state claims under the laws of other states on behalf of putative class members … is a matter to be decided under the rubric of Rule 23, not constitutional standing under Article III."); *In re Generic Pharm. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 831 (E.D. Pa. 2019) (denying motion to dismiss for lack of standing because it is "both proper and more efficient to consider whether [plaintiffs' may pursue their claims on behalf of the unnamed class members in the context of the class certification analysis required under Rule 23").

Plaintiffs bring claims on behalf of themselves, for which they have standing, and therefore satisfy the Article III requirements. Having established Article III standing as to the named Plaintiffs, there is "'no further separate class standing requirement in the constitutional sense.'" *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 307 (3d Cir. 1998) (quoting NEWBERG ON CLASS ACTIONS § 2.05, at 2-9 (3d ed. 1992)); *accord Neale*, 794 F.3d at 364 (3d Cir. 2015) ("[A] class action is permissible so long as at least one named plaintiff has standing."). Plaintiffs have properly brought claims under various states' laws on behalf of putative class members. The Court should address any issues as to predominance, adequacy, or typicality at the class certification stage. *See Rickman*, 2020 WL 3468250, at *11.

II. PLAINTIFFS DETAILED ALLEGATIONS ARE NOT "SHOTGUN PLEADINGS"

Defendants' persistence in characterizing Plaintiffs' Original Complaint, and now the FAC, as an impermissible "shotgun pleading" is simply wrong. *See* Manufacturer MTD at 22-26; Pharmacy MTD at 26 (incorporating manufacturers' argument).

A "shotgun" pleading is one that fails "to one degree or another … to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Weiland v. Palm Beach Cnty. Sheriff's Off.*, 792 F.3d 1313, 1323 (11th Cir. 2015). "A dismissal under Rule[] 8(a)(2) … is appropriate where 'it is virtually impossible to know which allegations of fact are intended to support which claim(s) for relief.'" *Id.* at 1325 (quoting *Anderson v. Dist. Bd. of Trustees of Cent. Fla. Cmty. Coll.*, 77 F.3d 364, 366 (11th Cir. 1996)). A defendant faced with a shotgun pleading should move under Rule 12(e) for a more definite statement, not seek dismissal on the grounds of alleged "shotgun" pleading issues. *See Weiland*, 792 F.3d at 1323.

Plaintiffs' allegations assert the grounds for relief against each Defendant and more than adequately meet the requirements of Fed. R. Civ. P. 8. *See Consumer Fin. Prot. Bureau v. RD Legal Funding, LLC*, 332 F. Supp. 3d 729, 770 (S.D.N.Y. 2018). As explained in the Background section, *supra*, and contrary to Defendants' protestations, the FAC laboriously recounts each Defendants' manufacture and sale of adulterated MCDs, including whose product each Plaintiff purchased (*see*, *e.g.*, FAC ¶¶ 12-27), that those products contained nitrosamines and were contaminated and adulterated as a result (*id.* ¶¶ 150-165), how each Defendant represented, wrongly, that MCDs were manufactured in compliance with cGMP (*id.* ¶¶ 159-170), specific examples of cGMP manufacturing violations or shortcuts by each Manufacturer Defendant (*id.* ¶¶ 171-247), and among other things each defendant's warranties and breach of same in selling contaminated product (*id.* ¶¶ 279-336). Ultimately, as the FAC makes clear,

every Defendant sold adulterated product that economically harmed Plaintiffs and other class members.

The FAC leaves no room for Defendants to guess what they are alleged to have done wrong. *See Clark v. McDonald's Corp.*, 213 F.R.D. 198, 234 (D.N.J. 2003) (Kugler, J.) ("[O]nce McDonald's is apprised as to which of its restaurants are at issue, it should be able determine from its own inspection or records its compliance or non-compliance with the ADA, as to enable it to either admit or deny the existence of such violations."). The FAC, in fact, largely tracks the structure and cadence of allegations in the Valsartan MDL, No. 1:19-MD-2875, pending before Judge Kugler in this District. Judge Kugler had no trouble moving beyond those defendants' similarly amorphous "shotgun" assertions and ruling on the motions to dismiss. There, as here, the plaintiffs' pleaded counts as to all defendants that incorporated the prior alleged factual allegations to avoid an absurdly large, unwieldly, and repetitive pleading (which Defendants no doubt would challenge, in goldilocks fashion, as being too big with too many counts). There is nothing wrong with this. *See, e.g.*, *Chin v. DaimlerChrysler Corp.*, 2005 WL 5121812, at *2 (D.N.J. Dec. 5, 2005) ("Incorporation by reference of all preceding allegations is such a common pleading technique that the Court does not feel comfortable in affording it the substantive significance that defendants seeks.").

Quite simply, there is no legitimate question that the robust Complaint satisfies Rule 8. Defendants were given fair notice of the claims against them, which is all that Rule 8 requires. *See, e.g.*, *Wynder v. McMahon*, 360 F.3d 73, 79 (2d Cir. 2004) ("[t]he key to Rule 8(a)'s requirements is whether adequate notice is given," and that "fair notice" is "that which will enable the adverse party to answer and prepare for trial, allow the application of res judicata, and identify the nature of the case so that it may be assigned the proper form of trial" (internal

quotation marks omitted)); *Hudak v. Berkley Grp., Inc.*, 2014 WL 354676, at *4 (D. Conn. Jan. 23, 2014) ("Nothing in Rule 8 prohibits collectively referring to multiple defendants where the complaint alerts defendants that identical claims are asserted against each defendant."). Indeed, the very fact that Defendants at each level were able to read and discern the FAC and move to dismiss it in a targeted manner, spanning ~110 collective pages of briefing between them, belies their arguments that the pleadings should be dismissed as unintelligible "shotgun" pleadings.

III. PLAINTIFFS' CLAIMS ARE NOT PREEMPTED, NOR ARE THEY BARRED BY THE PRIMARY JURISDICTION DOCTRINE

A. It Is Premature To Address Preemption At This Stage Of The Litigation

As an initial matter, preemption should not be addressed on a motion to dismiss. "Preemption is an affirmative defense, pleadings need not anticipate or attempt to circumvent affirmative defenses … This is why a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is not the appropriate vehicle for a preemption challenge: affirmative defenses typically turn on facts not before the court at [the dismissal] stage." *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1029 (N.D. Ill. 2016) (citations omitted); *see also In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.6 (3d Cir. 2016). Thus, dismissal is appropriate under Rule 12(b)(6) only when "preemption is manifest in the complaint itself." *See*, *e.g.*, *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 134 (3d Cir. 2018) (affirming denial of motion to dismiss on basis of preemption). Indeed, Defendants Teva, Aurobindo, CVS, Rite Aid, Walgreens, and Walmart unsuccessfully raised the same preemption arguments here in another pending litigation involving contaminated generic drugs, and Judge Kugler soundly rejected it. *See In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2020 WL 7418006, *7-9 (D.N.J. Dec. 18, 2020) ("*In re Valsartan I*"). This Court should do the same.

In addition, because there is a presumption against preemption, it can be applied only when preemption was "the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996); *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). Congress could not have intended to preempt the claims here, where the drug was contaminated via a manufacturing issue with a probable human carcinogen that was never approved by the FDA, let alone disclosed or made known to the public.

B. Impossibility Preemption Is Inapplicable

The Manufacturer Defendants do not identify precisely which form of preemption they claim applies here. Still, to the extent their generic preemption arguments can be construed as raising implied impossibility preemption, those arguments must fail. As recognized recently in this District, "impossibility preemption is a demanding defense rather than a pleading requirement … [that] places the burden on Defendants – and not Plaintiff – to support that defense with 'clear evidence.'" *Gremo v. Bayer Corp.*, 2020 WL 3496917, at *6 (D.N.J. June 29, 2020) (Hillman, J.) (denying motion to dismiss design and warning claims under NJPLA, as well as express warranty claim and punitive damages claim); *see Wyeth*, 555 U.S. at 573.

Here, there is no impossibility, as Defendants could have easily complied with the parallel state and federal requirements. Defendants could have manufactured the approved, uncontaminated MCDs, just as other pharmaceutical drug manufacturers did. It was also not impossible for Defendants to comply with the cGMPs, which required quality assurance and quality control measures that would have uncovered the contamination long before March 2020. One pharmaceutical manufacturer's ability to identify the contamination through quality assurance and quality control infrastructure is precisely why the contamination was even unearthed in the first place. Had Defendants done what other pharmaceutical manufacturers did, this would have eliminated the design and manufacturing defects, rendered the statements listing

the ingredients accurate, and dispensed with the need for the manufacturers to disclose that the drugs were contaminated – which triggered the recall of the drugs and an import alert.

The very basis for preemption in the context of generic drugs is the approval, based on the drug's "equivalence to a reference listed drug that has already been approved by the FDA." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). "[T]he proposed generic drug must be **chemically equivalent** to the approved brand-name drug." *Mutual Pharm. Co., Inc.*, *v. Bartlett*, 570 U.S. 472, 477 (2013) (emphasis added). The Supreme Court has defined a generic drug as, "a drug designed to be a **copy** of a reference listed drug (typically a brand name drug) and thus **identical** in active ingredients, safety, and efficacy." *Mensing*, 564 U.S. at 612 n.2 (emphasis added).[9] Here, Defendants' MCDs were not the equivalent, a copy, or identical to the reference listed drug, since they were contaminated with NDMA or other nitrosamines, so the affirmative defense of preemption is inapplicable by definition.

Defendants needed to stop selling the contaminated MCDs because "[o]nce a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making major changes to the qualitative or quantitative formulation of the drug product." *Bartlett*, 570 U.S. at 570.[10] Accordingly, when the contamination was disclosed to the FDA, the result was a recall. *See*, *e.g.*, *Lefaivre v. KV Pharm Co.*, 636 F.3d 935, 944 (8th Cir. 2011) (finding no preemption when the defendant "manufactured 'adulterated' medication in violation of cGMP requirements," and "issued a recall for all stocks of the medication sold to retailers"); *see also In*

[9] In *Mensing* the Supreme Court found that failure to warn claims alleging inadequacy of the generic drug's warnings were preempted since the generic manufacturer could not unilaterally change the warning. Of course, in that case the drug was not contaminated with a carcinogen and was the generic equivalent of the reference listed drug.

[10] This differs from *Bartlett*, where the drug at issue was the approved generic equivalent of the brand drug.

re MDL 2700 Genentech Herceptin (Trastuzumab) Mktg. & Sales Prac. Litig., 960 F.3d 1210, 1240 (10th Cir. 2020) (concluding that the defendant "failed to satisfy its burden of establishing that impossibility pre-emption applies to plaintiffs' claim," when the defendant had manufactured the drug as plaintiffs alleged was required).

C. Implied Preemption Is Inapplicable

To the extent Defendants seek to invoke implied preemption, those arguments must also fail. Implied preemption is a narrow defense. The Supreme Court has defined implied preemption to focus essentially on "**fraud-on-the-FDA claims**," which are not made here. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (emphasis added). Defendants concede that implied preemption only applies, "if the state-law claim depends on concepts or standards that exist "**solely**" because of the FDCA, [and] it does not flow from a pre-existing state-law duty." Manufacturer MTD at 26 (emphasis added) (citing *Buckman*, 531 U.S. at 352-353); *see also Yocham v. Novartis Pharms. Corp.*, 736 F. Supp. 2d 875, 885 (D.N.J. 2010) (Simandle, J.) (explaining that "the only way to make sense of the concern in *Buckman* is to understand it to be about the unique increase in incentive created by a tort in which the **sole** conduct element was such misrepresentation to the FDA") (emphasis added).

Here, Plaintiffs' claims have an independent state law basis, and Plaintiffs explicitly do not seek to enforce FDA regulations as the sole basis for recovery. The FAC, for instance, explicitly states at paragraph 149: "Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law." It also alleges that "by referring to their drugs as 'metformin' Defendants were making false statements regarding their MCDs." FAC ¶ 164. It also alleges that "[e]ach Defendant owed a duty to

Plaintiffs and the Class to use and exercise reasonable and due care in the manufacturing of its MCDs." *Id.* at ¶¶ 491, 501, 511, 519.

A recent New Jersey Supreme Court case is instructive. In *In re Reglan Litigation*, 226 N.J. 315 (2016), generic manufacturers failed to use the label approved by the FDA for the brand name product. The court found the failure to warn claim was not preempted because "[a] violation of the FDCA's sameness requirements is not an element of plaintiffs' claims. Plaintiffs' claims do not exist solely by virtue of a federal regulatory scheme...plaintiffs are availing themselves of protections long available under this State's product-liability law … **Plaintiffs' claims run parallel to the FDCA's sameness requirement for labeling warnings, but they are not based on that requirement**." *Reglan,* 226 N.J. at 343 (emphasis added); *see also Laverty*, 197 F. Supp. 3d at 1034 (rejecting *Buckman* motion where no allegation that defendant made misrepresentations or omissions to FDA on PMA application) (citing *Bausch v. Stryker Corp*., 630 F.3d 546, 557 (7th Cir. 2010)); *Williams v. Smith & Nephew*, 123 F. Supp. 3d 733, 746-747 (D. Md. 2015) ("In sum, the only claims impliedly preempted are those that are based on the violation of federal duties that have no freestanding basis in Maryland tort law.").

The claims here are traditional state law claims. But nowhere in the FAC do Plaintiffs seek to impose additional obligations on Defendants that conflict with, or pose an obstacle to, compliance with federal requirements. That federal regulations also required the drugs to be manufactured to yield the generic equivalent, without nitrosamine contamination, and that the manufacturer not sell adulterated drugs, is not the basis for the claim. Those are simply parallel federal requirements. *See, e.g.*, *In re Valsartan I*, 2020 WL 7418006, at *8-9 (parallel state duty not to sell contaminated drug were not impliedly preempted); *see also Wyeth*, 555 U.S. at 564 (FDCA did not impliedly preempt state law claims seeking to enforce parallel state law

requirements). That these are merely parallel federal requirements is even true "if proving those independent state law claims will rely, in part, on evidence that a federal requirement was violated." *Williams*, 123 F. Supp. 3d at 747 (emphasis added); *see also In re Valsartan I*, 2020 WL 7418006, at *8-9; *Lechler v. 303 Sunset Ave. Condo. Assoc., Inc.*, 452 N.J. Super. 574, 584 (App. Div. 2017); *Carnero v. Deitert*, 10 F. Supp. 2d 440, 444 (D.N.J. 1996) (Lifland, J.); *cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444 (2005).

A similar analysis applies to the claims premised on Defendants' statements and representations, such as the state law express warranty claims. *See Gremo*, 2020 WL 3496917, at *9. This holds as well for the allegations that MCDs were misbranded, violated the duty of sameness, and other violations of federal regulations. *See, e.g.*, *In re MDL 2700 Genentech Herceptin (Trastuzumab) Mktg. & Sales Prac. Litig.*, 960 F.3d 1210, 1234, 1240 (10th Cir. 2020) (reversing dismissal of state law claims against drug manufacturer for failing to ensure each vial of drug contained labeled amount of active ingredient, and finding conflict and impossibility preemption inapplicable); *Lefaivre v. KV Pharm Co.*, 636 F.3d 935, 944 (8th Cir. 2011) (reversing dismissal of consumer state law class action claims against hypertension medication manufacturer for failure to comply with cGMP, and finding preemption inapplicable); *In re Digitek Prods. Liab. Litig.*, 2009 WL 2433468, at *12-13 (S.D. W. Va. Aug. 3, 2009) (finding state law claims against Mylan for manufacture and sale of misbranded or adulterated drugs were not preempted); *Aetna Inc. v. Insys Therapeutics, Inc.*, 324 F. Supp. 3d 541, 555 (E.D. Pa. 2018) (state law claims by TPP for reimbursement of off-label drug use not preempted).

Finally, while not a claim alleged here, the same analysis above also would apply to a state law claim premised on the failure to warn a third party, including the FDA. "State law failure to warn claims – premised on [Restatement] Section 388 – which focus on a

manufacturer's failure to report adverse events to the FDA, are not preempted." *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 359-60 (D. Del. 2019) (citing *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 899-900 (M.D. Pa. 2016) ("this duty is parallel to FDA reporting requirements.")); *see also McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 837-838 (E.D. Pa. 2016) (applying Section 388 to permit claim based on duty to warn third party, which is "parallel" to FDA reporting requirements). New Jersey courts also apply Section 388. *Arcell v. Ashland Chem. Co.*, 378 A.2d 53, 65 (N.J. Super. Ct. 1977), *Torsiello v. Whitehall Labs.*, 398 A.2d 132, 137 n.2 (N.J. App. Div. 1979), *McGarvey v. G.I. Joe Septic Serv., Inc.*, 679 A.2d 733, 743 (N.J. App. Div. 1996). These principles—that violation on a parallel duty does not run afoul of implied impossibility or conflict preemption—apply equally to the claims alleged here.

D. The Primary Jurisdiction Doctrine Is Inapplicable

Defendants contend that Plaintiffs' claims should be dismissed based upon the primary jurisdiction doctrine. This is wrong.

As an initial matter, as with their preemption arguments, Defendants Teva, Aurobindo, CVS, Rite Aid, Walgreens, and Walmart unsuccessfully raised the same preemption arguments here in another pending litigation involving contaminated generic drugs. That court soundly rejected Walmart's preemption argument. *See In re Valsartan I*, 2020 WL 7418006, at *11-24 (rejecting primary jurisdiction argument in litigation involving contaminated generic drugs). Once again, this Court should do the same, for the same reasons.

In any event, "[t]he doctrine of primary jurisdiction applies … comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." *Raritan Baykeeper v. NL Industries, Inc.*, 660 F.3d 686, 691 (3d Cir. 2011). The

doctrine is reserved for a "limited set of circumstances" that "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015). When determining the applicability of the primary jurisdiction doctrine, courts consider four factors: (1) whether the question "is within the conventional experience of judges" or instead "involves technical or policy considerations within the agency's particular field of expertise"; (2) whether the question "is particularly within the agency's discretion"; (3) whether there is "a substantial danger of inconsistent rulings"; and (4) whether a "prior application to the agency has been made." *Baykeeper*, 660 F.3d at 691 (internal quotations omitted). None of these factors are satisfied here.

First, Defendant's liability to Plaintiffs is well within the conventional experience of judges and this Court. Not every case that implicates the potential expertise of federal agencies warrants invocation of primary jurisdiction. Rather, "[f]ederal courts have a 'virtually unflagging obligation … to exercise the jurisdiction given them.'" *Id.* (quoting *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976)). Although continued FDA investigation into Defendants' MCDs may occur, the FDA has already established that Defendants MCDs contained unsafe levels of NDMA and NDEA, resulting in a recall. Thus, the issues before the Court concerning the liability Defendants do not fall within an agency's discretion. *See Baykeeper*, 660 F.3d at 692 (court retaining jurisdiction, explaining that the plaintiff's "suit does not amount to a 'collateral attack' on an NJDEP decision, nor does it seek a remedy that necessarily conflicts with any agency order"); *Business Edge Grp., Inc. v. Champion Mortg. Co.*, 519 F.3d 150, 154 (3d Cir. 2008) (holding that it was "more appropriate to remand

to the District Court for further proceedings than to transfer it to the agency because we find that the meaning of the regulation can be determined from its text").

Second, even though the regulation of drug products is within the FDA's realm of expertise, this does not itself mean that the primary jurisdiction doctrine should be applied. *See Grogan v. Aaron's Inc.*, 2018 WL 6040195, at *7 (N.D. Ga. Oct. 26, 2018) ("While it is beyond cavil that the issues implicated in this case … necessarily fall within the FCC's purview, that does not lead to the inexorable conclusion that they are beyond the ken of this Court to analyze and adjudicate, even in the absence of binding regulatory guidance from the FCC."). That is especially true where, as here, the other three factors support denial:

> Some of the factors weigh in favor of application of primary jurisdiction, but abstention is the exception rather than the rule. Federal courts have an obligation to exercise their jurisdiction. Because this Court is competent to decide the matters that may eventually be brought by the parties, the Court concludes that this is not one of those exceptional cases that calls for primary jurisdiction abstention at this time.

Baum v. ADT LLC, 2018 WL 5255219, at *4 (W.D. Pa. Oct. 22, 2018). This is not an "exceptional case" requiring application of the primary jurisdiction doctrine. *Id.* Further, if Defendants' primary jurisdiction doctrine argument were correct, no pharmaceutical or medical device case would ever proceed in federal court, which is not the case. *See*, *e.g.*, *Gubaala v. CVS Pharmacy, Inc.*, 2016 WL 1019794, at *16 (N.D. Ill. Mar. 15, 2016) (refusing to dismiss or stay claims against CVS under primary jurisdiction where CVS was alleged to have sold mislabeled protein powder supplements); *Torres-Hernandez v. CVT Prepaid Solutions, Inc.*, 2008 WL 5381227 (D.N.J. Dec. 17, 2008) (Wolfson, J.) (rejecting defendant's argument regarding primary jurisdiction, and holding that "[t]aken to its logical extreme, Defendant's proposed application of the doctrine would permit a pharmaceutical company to avoid negligence claims in federal court by invoking the Food and Drug Administration's authority (putting aside any preemption issues),

or force a state court to defer consumer fraud actions against a commercial bank due to Federal Reserve oversight").

Third, there is no danger of inconsistent rulings because all cases concerning the contaminated MCDs have been consolidated before this Court (and over Defendants' opposition).

Finally, "[t]he fourth prong … contemplates that a **party** to the present suit made prior application to the [government agency in question]." *Central Telephone Co. of Virginia v. Sprint Communications Co. of Virginia*, 759 F. Supp. 2d 772, 788 (E.D. Va. 2011), *aff'd*, 715 F.3d 501 (4th Cir. 2013) (emphasis in original); *Demmick v. Cellco P'ship*, 2011 WL 1253733, at *6 (D.N.J. Mar. 29, 2011) (Linares, J.) (holding that the fourth factor weighed against primary jurisdiction because "Plaintiffs have made no prior application to the FCC"); *Pennsylvania Elec. Co. v. United Foundry Co.*, 2009 WL 2460775, at *5 (W.D. Pa. Aug. 11, 2009) (holding that the fourth factor weighed against primary jurisdiction because Pennsylvania Electric was "not aware of any application being made by the Appellee or the Purchaser to the Pennsylvania PUC") (internal quotations omitted). No Defendant has made such an application to the FDA here, and so the factor does not apply.

E. The Drug Supply Chain Security Act Does Not Preempt Plaintiffs' Claims

The Retail Pharmacy Defendants argue that the Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. §§ 360eee, *et seq.*, preempts all of Plaintiffs' claims against them. *See* Retail Pharmacy Br. at 6-8. DSCSA preemption, however, is very narrow and does not apply here.

Yet again, CVS, Rite Aid, Walgreens, and Walmart made this identical argument in the Valsartan MDL, and Judge Kugler soundly rejected it. *See In re Valsartan I*, 2020 WL 7418006,

at *7-11. Once again, this Court should follow Judge Kugler's sound reasoning in *In re Valsartan*.[11]

Moreover, the DSCSA preempts *only* state or local regulations that establish "requirements for tracing products through the distribution system," as highlighted below:

> (a) PRODUCT TRACING AND OTHER REQUIREMENTS. Beginning on November 27, 2013, no State or political subdivision of a State may establish or continue in effect any **requirements for tracing products through the distribution system** (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) **which are inconsistent with, more stringent than, or in addition to, any requirements** applicable under section 353(e) of this title or this part (or regulations issued thereunder), or which are inconsistent with—
>
> > **(1)** any waiver, exception, or exemption pursuant to section 360eee or 360eee-1 of this title; or
> >
> > **(2)** any restrictions specified in section 360eee-1 of this title.

1 U.S.C. § 360eee-4(a) (emphases added).

Defendants also failed to cite the full relevant language of the statute. Subsection 4(e) expressly states:

> **Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing** as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 353(e) of this title or this part (or regulations issued thereunder).

[11] The best these Defendants muster here is to parenthetically assert "Judge Kugler erred." *See* Pharmacy MTD at 12 n.9. Notably, they never sought reconsideration or interlocutory appeal of Judge Kugler's well-reasoned opinion. The Retail Pharmacy Defendants' weak attempt to distinguish *In re Valsartan I* also fails because express preemption clauses do not apply broadly. Instead, they must be confined to their wording. *See*, *e.g.*, *Pennsylvania v. Navient Corp.*, 967 F.3d 273, 288-90 (3d Cir. 2020) (narrowly construing preemption clause and refusing to expand its scope beyond plain reading of clause).

21 U.S.C. § 360eee-4(e) (emphasis added).

Thus, unless a cause of action under state law seeks to regulate "product tracing" or licensure requirements, the DSCSA's preemption clause does not apply.[12] Accordingly, because none of Plaintiffs' claims hinge on whether these Defendants properly "traced" the products, the claims against Retail Pharmacy Defendants are not preempted.

IV. THE NEW JERSEY, TPP AND INDIANA PLAINTIFFS' CLAIMS ARE NOT SUBSUMED BY THE NEW JERSEY OR INDIANA PRODUCT LIABILITY ACTS

The Manufacturer Defendants unpersuasively claim that the New Jersey Products Liability Act ("PLA") subsumes the claims of the New Jersey Consumer Plaintiffs (Brzozowski and Harris) and Plaintiff MSPRC for breach of implied warranty, unjust enrichment, negligence, and negligence per se. Mfr. Br. at 38-43.[13] The Third Circuit has recognized that, for purposes of subsumption under the PLA, "[h]ow a given claim must be pled … depends on what is at the 'heart of plaintiffs' case'—the underlying theory of liability." *Sun Chem. Corp.*

---

[12] Even if this were not the case, the DSCSA's narrow preemption clause cannot displace all state law. Instead, it only incorporates familiar conflict-preemption principles and displaces state law that is "inconsistent with, more stringent than, or in addition to" the DSCSA's requirements.

[13] The Manufacturing Defendants mistakenly argue that the PLA "is presumed to apply to MSPRC's claims." Manufacturer MTD at 38 n.16. They fail to apply the "most significant relationship test" and assume that the PLA applies because it is "the assignee of healthcare benefit providers from multiple states alleged to have paid for MCDs in nearly every state." *Id.* While it is true "[w]hen each state is interested in the application of its laws and the application of the foreign state's law would frustrate the purposes of the forum state, the presumption is to apply the law of the forum," *Lebegern v. Forman*, 471 F.3d 424, 433 (3d Cir. 2006), the Manufacturing Defendants have performed no choice of law analysis showing the relative states' interests or how the application of a foreign states' law would frustrate the forum's law. *See, e.g.*, *Alley v. MTD Prod., Inc*, 811 F. App'x 772, 773-75 (3d Cir. 2020). Because they bear the burden of persuasion on their motion to dismiss, and have not presented a choice of law analysis or arguments as to this Court's proper interpretation of the applicable laws, their PLA-related arguments as to MSPRC should fail for this reason alone. *See E. Concrete Materials, Inc. v. Jamer Materials Ltd.*, 2019 WL 6734511, at *9 (D.N.J. Oct. 25, 2019), *report and recommendation adopted*, 2019 WL 6726476 (D.N.J. Dec. 10, 2019); *Bellak v. Wells Fargo & Co.*, 2017 WL 3425177, at *2 (D.N.J. Aug. 9, 2017).

v. Fike Corp., 981 F.3d 231, 236 (3d Cir. 2020) (quoting *Sun Chem. Corp. v. Fike Corp*., 235 A.3d 145, 156 (N.J. 2020)). "'This Court has repeatedly held that "claims alleging that a plaintiff 'did not get what [they] paid for' are not subsumed by the PLA.'" *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig*., 2021 WL 364663, at *10 (D.N.J. Feb. 3, 2021) ("*In re Valsartan V*") (quoting *Gorczynski v. Electrolux Home Prods., Inc.*, 2019 WL 5304085, at *3 (D.N.J. Oct. 18, 2019)). "Additionally, the Third Circuit explains, where the New Jersey PLA does not cover the type of damages alleged, the 'PLA cannot subsume that which it explicitly excludes from its coverage.'" *In re Valsartan V*, 2021 WL 364663, at *10 (citing *Estate of Edward W. Knoster v. Ford Motor Co.*, 200 F. App'x 106, 116 (3d Cir. 2006)). And the Third Circuit and the New Jersey Supreme Court have also held that whether a claim is subsumed by the PLA is determined by looking at the "whether the claim is based upon a product's manufacturing, warning, or design defect and therefore covered by the PLA." *Sun Chem. Corp.*, 981 F.3d at 237 (citing *Sun Chem. Corp.*, 235 A.3d at 156).

Defendants ignore that the heart of the Plaintiffs' claims, or their underlying theories of liability, is overpayment for a product that was other than what Defendants represented it to be, or receipt of a product that had diminished or no value. *See*, *e.g.*, FAC ¶ 1; *see also id*. ¶¶ 6-18, 27, 290, 294, 346, 373-76, 382-87, 393-96, 402, 470, 476, 479-82, 485-88, 493-98, 501-08, 511-16, 519-24, 554, 558, 571-72, 583-85.[14] These claims do not rest on allegations of any "manufacturing, warning, or design defects" concerning the metformin-containing drugs at issue. Plaintiffs' breach of warranty claims, for example, are based on misrepresentation or

[14] *See Volin v. Gen. Elec. Co*., 189 F. Supp. 3d 411, 418 (D.N.J. 2016) (upholding as not subsumed by PLA claims for breach of implied warranty, consumer fraud, and unjust enrichment where "[t]he common theme . . . is not that the product caused harm to plaintiff or her property" but that plaintiff "did not get what she paid for."); *Sun Chem. Corp. v. Fike Corp*., 2015 WL 881961, at *3 (D.N.J. Mar. 2, 2015) (claims not subsumed by PLA where allegations are that seller misrepresented suitability of product) (citing cases).

omission-related allegations which assert that Plaintiffs bought a product with no value: "Defendant knew or should have known that its MCDs were being … sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs," that Defendant "impliedly warranted that their MCDs were of merchantable quality and fit for that purpose," and that Plaintiffs bought a product that had diminished or no market value. FAC ¶¶ 383, 387, 394, 396. This Court has upheld as not subsumed by the PLA similar claims. *See*, *e.g.*, *Palmieri v. Intervet Inc.*, 2021 WL 2205854, at *7 (D.N.J. June 1, 2021) (claim for breach of implied warranty claim not subsumed by PLA where plaintiffs alleged drug "was not in merchantable condition and not fit for the ordinary purpose for which it was intended, and that they paid a price that they otherwise would not have had defendant not represented it as "generally safe without serious side effects").

Moreover, Plaintiffs' claims do not involve "harm" that constitutes physical injury from use of the drug. Nor do they involve harm as defined by the PLA. *See* N.J.S.A. § 2A:58C-1(b)(2).[15] The Manufacturer Defendants' advertising and omissions (*see*, *e.g.*, FAC ¶¶ 160-64, 279, 285, 359, 416-24) caused Plaintiffs' injuries (financial harm), not the ingestion of Metformin. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2018 WL 4030586, at *4 (N.D. Ill. Aug. 23, 2018) (claim subsumed under NJ PLA where advertising could not have caused injuries unless drug Androgel did).

[15] The PLA's definition of harm "represent[s] a codification of the economic loss rule," and the PLA therefore does not apply to the loss of a product itself or other purely economic harm. *Dean v. Barrett Homes, Inc.*, 8 A.3d 766, 771 (N.J. 2010) ("Simply put, the [Products Liability] Act is not concerned with providing a consumer with a remedy for a defective product per se; it is concerned with providing a remedy for the harm or the damage that a defective product causes to people or to property."); *Ford Motor Credit Co. v. Mendola*, 48 A.3d 366, 374 (N.J. App. Div. 2012).

Defendants fail to show any allegations indicating that the theory of Plaintiffs' case involves Metformin physically injuring any Plaintiffs.[16]

Alternatively, the essence or core of Plaintiffs' claim is that Metformin was contaminated by other substances, thus showing that Plaintiffs seek damages for destruction of the product itself, which is recoverable under the PLA.[17] *See* FAC ¶¶ 8-10, 179-82, 223, 260-71; *id.* at ¶ 155 n.50. Plaintiffs purchased MCDs that, based on their contamination, were so flawed and unmerchantable that they had a significantly diminished or no intrinsic market value, *id*. ¶¶ 387, 396, or led to Plaintiffs being unjustly deprived of money as a result of improper amounts paid to Defendants. *Id*. ¶¶ 12, 14, 346, 387, 396, 481, 487; *see also id.* ¶¶

[16] *See generally Hindermyer v. B. Braun Med. Inc*., 419 F. Supp. 3d 809, 820 (D.N.J. 2019) ("Significantly, however, and unlike the plaintiff in *Montich*, her alleged damages arise solely from her 'serious physical injuries' and the 'medical costs and expenses' which are required 'to treat and care for [those] injuries.'"); *id.* at 821 ("Here, Plaintiff's fraudulent misrepresentation claim, as asserted in Count VIII of the Complaint, alleges: '[a]s a direct and proximate consequence of Defendants' fraudulent misrepresentations, the Plaintiff sustained serious personal injuries'"); *Gorczynski v. Electrolux Home Prod., Inc.*, 2019 WL 1894915, at *3 (D.N.J. Apr. 29, 2019) (claims not subsumed by PLA where "Plaintiff neither alleges nor seeks any damages for physical harm caused by the handle defect (such as burns to his hand)"); *Flint Grp. N. Am. Corp. v. Fox Indus. Inc*., 2017 WL 1838763, at *5 (D.N.J. May 5, 2017) ("The Complaint is replete with allegations of harm caused by a defective product, the Alumina Shot."); *id.* at *7 ("Plaintiff does not seek recovery for damage to the defective product itself."); *Sun Chem. Corp. v. Fike Corp*., 2017 WL 6316644, at *15 (D.N.J. Dec. 11, 2017) ("the Fike System was defective and caused harm, *to both person* and property. Such a claim falls clearly within the scope of the PLA as a products-based action.") (emphasis added).

[17] On its face, the PLA does not apply when a plaintiff alleges damage to the product itself rather than to a person or other property. The PLA is also specific that "harm" means actual physical damage to property other than the product itself. *See* N.J.S.A. § 2A:58C-1(b)(2) ("'Harm' means (a) physical damage to property, *other than to the product itself*; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.") (emphasis added). *See Mendez v. Shah*, 28 F. Supp. 3d 282, 302 n.10 (D.N.J. 2014) ("Claims for 'physical damage … to the product itself' are not 'product liability action[s]' because the PLA specifically excludes such damage from its definition of 'harm.' ") (citing *Estate of Edward W. Knoster*, 200 F. App'x at 116).

478-83. Under such circumstances, the damage is to the Metformin product itself, rather than to "other property" for PLA purposes.[18] Despite bearing the initial burden of persuasion, the Manufacturer Defendants present no argument as to these allegations, and they should not be permitted to do so for the first time on reply.

The Manufacturer Defendants recognize that a personal injury caused by a defect is necessary for a PLA claim. Manufacturer MTD at 41. Indeed, the New Jersey Supreme Court has held that an actual physical injury is required for the PLA to apply. *See Sinclair v. Merck & Co*., 948 A.2d 587, 595 (N.J. 2008). Yet the Manufacturer Defendants ignore that the PLA does not apply when, as here, the Plaintiffs allege damage to the product itself, or purely economic damages. *See Sun Chem. Corp.*, 235 A.3d at 150 n.2; *Flint Grp. N. Am. Corp. v. Fox Indus. Inc*., 2017 WL 1838763, at *6, *8 (D.N.J. May 5, 2017) ("In light of [New Jersey Appellate Division and Supreme Court] cases, the Court concludes that the PLA does not apply when a party is seeking 'purely' or 'only' economic damages."). "As explained by the Third

[18] *See Gorczynski*, 2019 WL 5304085, at *3 ("Thus, where a CFA claim relates exclusively to economic damages resulting from harm to the product itself, it cannot be precluded and subsumed by the PLA."); *Kuzian v. Electrolux Home Prod., Inc*., 937 F. Supp. 2d 599, 608 (D.N.J. 2013) (where harm is to product itself, PLA does not apply); *Arlandson v. Hartz Mountain Corp*., 792 F. Supp. 2d 691, 703 (D.N.J. 2011) (distinguishing claims not subsumed by PLA because "product itself was destroyed or harmed by some defect or problem with product" and noting that "[h]ere, Plaintiffs allegations are based on the harm caused to their pets by the alleged defects in the Products, not based on any harm caused to the Products themselves"); *Ford Motor Credit Co. v. Mendola*, 48 A.3d 366, 374 (N.J. App. Div. 2012) ("Product Liability Act and common law tort actions do not apply to damage caused to the product itself"); *Wisconsin Pharmacal Co., LLC v. Nebraska Cultures of California, Inc.*, 876 N.W.2d 72, 82 (Wis. 2016) (combining defective ingredient with other ingredients and incorporating them into Pharmacal probiotic tablet formed integrated system, resulting in damage to product itself rather than damage to other property); *Est. of Knoster v. Ford Motor Co*., 2008 WL 5416399, at *9 n.4 (D.N.J. Dec. 22, 2008) ("Neither [*McDarby* nor *Sinclair*] changes the critical fact that economic damages for destruction of the product are not recoverable under the PLA."); *see also Dean v. Barrett Homes, Inc*., 8 A.3d 766, 773 (N.J. 2010) (noting that Third Circuit and "federal courts have employed th[e] [integrated product] theory when called upon to apply New Jersey law as well," and citing cases).

Circuit, where the PLA does not cover the type of damages alleged, the 'PLA cannot subsume that which it explicitly excludes from its coverage.'" *Gorczynski*, 2019 WL 5304085, at *3 (quoting *Knoster*, 200 F. App'x at 116).

The Manufacturer Defendants selectively cite, and misconstrue in their favor, the allegations to try to characterize the Plaintiffs' claims as subsumed by the PLA. *See* Manufacturer MTD at 40. But—even if an actual physical injury was not required to be considered subsumed by the PLA— "[t]o the extent Plaintiff describes other harms that would lead to the claim being subsumed by the PLA, such as the risk of physical injury, these harms do not form the 'core issue' or 'heart' of the lawsuit … They are only mentioned sporadically throughout the complaint, and they are not discussed in the section where Plaintiff details the purported harms and damages." *Rosenthal v. SharkNinja Operating LLC*, 2016 WL 5334662, at *3 (D.N.J. Sept. 22, 2016) (citation omitted); *see also*, *e.g.*, FAC ¶¶ 6-18, 27, 290, 294, 346, 373-76, 382-87, 393-96, 402, 470, 476, 479-82, 485-88, 493-98, 501-08, 511-16, 519-24, 554, 558, 571-72, 583-85.[19]

[19] The central decisions relied on by the Manufacturer Defendants are not on point because in those cases, the plaintiffs alleged actual physical injuries, *McDarby v. Merck & Co.*, 949 A.2d 223, 248, 278 (N.J. App. Div. 2008), or the court dismissed the plaintiffs' PLA claims for lack of a physical injury, *Sinclair v. Merck & Co.*, 948 A.2d 587, 595 (N.J. 2008). *Sun Chem. Corp.*, 235 A.3d 145, is similarly unavailing. There, the court held that "the PLA will not bar a [NJ]CFA claim alleging express or affirmative misrepresentations, *id.* at 156, even though the product there malfunctioned, resulting in an explosion that injured numerous employees of the plaintiff and physical damage to its property, *id*. at 326. In *DeBenedetto v. Denny's, Inc.*, 23 A.3d 496 (N.J. Super. Ct. 2010), *aff'd Unpub.*, 2011 WL 67258 (N.J. App. Div. Jan. 11, 2011), the essence of the case included the fact that the plaintiff had suffered a physical injury. *See id*. at 501-02. Also, in contrast to here, the plaintiff did not allege that the defendant made any affirmative misrepresentations; the court held that the defendant's non-disclosures constituted a failure to warn claim, a "classic articulation of tort law duties'" that is within the theories falling under the PLA. *See id*. at 500. *DeBenedetto* also contradicts *Sinclair*'s requirement that an actual physical injury is necessary for PLA claims. In addition, in *DeBenedetto*, whether the damage was to the product itself rather than to other property was not before the court. Even if relevant, as a Law Division decision, *Debenedetto* is not binding and owed no deference here. *See Houbigant, Inc. v. Fed. Ins. Co.*, 374 F.3d 192, 199, 199 n.9 (3d Cir. 2004).

Under the pleading requirement that all reasonable inferences and the allegations be generously construed in a plaintiffs' favor on a motion to dismiss, courts in this District have declined to dismiss complaints when, as here, the claims concerned overpaying for a product based on a defendant's representations or omissions and allegations of damage to the product itself, or where, as a result of the defendant's conduct, the product had diminished or no value.[20] Thus, Plaintiffs' claims are not preempted under the PLA.

Furthermore, for the reasons discussed above, the Manufacturing Defendants' argument that Plaintiffs' breach of implied warranty claims under Indiana and New Jersey law are subsumed by the PLA, Manufacturer MTD at 42-43, is unpersuasive. Here, Plaintiffs allege that each Defendant knew "that its MCDs were being manufactured and sold for the intended purpose of human consumption as a therapeutic equivalent to their RLDs," that Defendants "impliedly warranted that their MCDs were of merchantable quality and fit for that purpose," and that Plaintiffs bought a product that had diminished or no market value. FAC ¶¶ 383, 387, 394, 396. Such allegations are enough to plead the challenged breach of implied warranty claims. *See Palmieri*, 2021 WL 2205854, at *7; *see also In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, --- F. Supp. 3d ---, 2021 WL 1050910, at *41-42 (D.N.J. Mar. 19, 2021) (Martinotti, J.) (contract-based breach of implied warranty claims not subsumed by Indiana PLA where plaintiff alleged defendant "impliedly warranted to Plaintiff that the

[20] *See Sun Chem. Corp.*, 2015 WL 881961, at *4 (declining to dismiss at pleading stage complaint where harm was sufficiently alleged as representation based and court could not determine, absent discovery, whether core issue was harmfulness of product rather than representations regarding its suitability); *Beyerle v. Wright Med. Tech. Inc.*, 2014 WL 12623029, at *2 (D.N.J. Dec. 23, 2014) (noting Rule 12(b)(6) pleading standard and declining to dismiss complaint where plaintiff alleged harm to medical device product itself and that he expended a substantial sum of money he otherwise would not have expended; "if discovery reveals that the 'heart' of Plaintiff's case is the harm caused by the product, rather than the harm caused to the product itself, Defendants may move for summary judgment on the CFA claim") (citing cases); *Shannon v. Howmedica Osteonics Corp.*, 2010 WL 1492857, at *2 (D.N.J. Apr. 14, 2010).

defective implants were of merchantable quality and safe for their ordinary and intended use in the human body as breast implants and tissue expanders"); *Gorczynski*, 2019 WL 1894915, at *2-3 ("Courts in the District of New Jersey have held that claims alleging that a plaintiff 'did not get what [they] paid for," such as breach of implied warranty … are also not subsumed by the PLA."); *Gorczynsk*, 2019 WL 5304085, at *2-4 (same).

V. PLAINTIFFS ADEQUATELY PLEAD EXPRESS WARRANTY, IMPLIED WARRANTY, AND MAGNUSON-MOSS WARRANTY CLAIMS AGAINST THE MANUFACTURER DEFENDANTS

The FAC validly states causes of action for breach of express and implied warranties under numerous state laws, as well as violations of the Magnuson-Moss Warranty Act.[21] To bolster their losing dismissal arguments, Defendants have presented an assortment of inapposite case law and selective readings of the allegations.

A. Plaintiffs Are Not Required To Address State Law Claims Not Raised By Defendants In Their Motions To Dismiss

The Manufacturer Defendants make sweeping statements about the viability of Plaintiffs' warranty claims in their briefs, but only list a few states where they claim Plaintiffs' warranty claims are precluded (California, New York, New Jersey, and Indiana). In essence, The Manufacturer Defendants try to engage in "for example"-type arguments hoping that this Court will apply such arguments more broadly than the specific examples given. There is no obligation

[21] Because the viability of the Magnuson-Moss claims depends on applicable state law, and because the state warranty claims are viable for the reasons discussed in this section, so too, are the Magnuson-Moss claims. *See*, *e.g.*, *Miller v. Chrysler Grp. LLC*, 2014 WL 12617598, at *6 (D.N.J. June 30, 2014) ("Plaintiffs' MMWA claim survives along with the implied warranty claim discussed above."); *Cali v. Chrysler Grp. LLC*, 2011 WL 383952, at *4 (S.D.N.Y. Jan. 18, 2011) ("[C]laims under the Magnuson–Moss Act stand or fall with the express and implied warranty claims under state law."); *Lewand v. Mazda Motor of America, Inc.*, 2017 WL 8117764, at *3 (C.D. Cal. Nov. 8, 2017) ("Because the Court does not dismiss the warranty claim, it also does not dismiss the MMWA claim.").

for a plaintiff to affirmatively address non-raised arguments or aspects of claims with no specific dismissal argument made (e.g., specific states not raised by Defendants).

B. Plaintiffs Adequately Plead New Jersey And Indiana Implied Warranty Claims

The Manufacturer Defendants assert that Plaintiffs' implied warranty claims under New Jersey and Indiana law fail because Plaintiffs did not allege "any present physical harm" or "depriv[ation] of their MCDs' therapeutic benefits." Manufacturer MTD at 42.) These supposed pleading requirements, however, are simply not part of New Jersey or Indiana implied warranty laws. The Court should follow Judge Kugler's analysis in *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, 2021 WL 222776 (D.N.J. Jan. 22, 2021) ("*In re Valsartan III*") (also pertaining to generic pharmaceutical nitrosamine contamination), in which the court denied the manufacturer defendants' motion to dismiss economic loss warranty claims. Specifically, Judge Kugler stated the following:

> This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for. Further, contaminated drugs do create a present injury because their sale should never have occurred. Accordingly … individual consumer plaintiffs and third party payor plaintiffs need not demonstrate a 'benefit of the bargain' theory of economic damages to adequately plead a breach of implied warranty.

In re Valsartan III, 2021 WL 222776, at *16.

By contrast, the cases cited by Defendants are off point.

The lone Indiana case cited by Defendants is *Irmscher Suppliers, Inc. v. Shuler*, which states that Indiana law requires a showing that the product is "fit for the ordinary purposes for which such goods are used." 909 N.E. 2d 1040, 1048 (Ind. Ct. App. 2009). The fact is that the adulterated MCDs at issue are in fact not fit for ordinary purposes, for the reasons stated by

Judge Kugler *supra* in his *In re Valsartan* decision. Several other decisions from courts have found that adulterated drugs carry zero economic value. *See*, *e.g.*, *In re Valsartan III*, 2021 WL 222776, at *16 ("[C]ontaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for. Further, contaminated drugs do create a present injury because their sale should never have occurred."); *see also* Argument § I.A at 19 n.7, *supra* (discussing *Debernardis*, *Muransky*, *Franz*, *In re Aqua Dots, Blue Cross*, *Yachera*, and *Hope*).

Defendants' New Jersey cases are just as off point. In *Hoffman,* the *pro se* plaintiff (who did not oppose the motion to dismiss) merely alleged that the supplement he received contained a small amount of lead and did not allege that the presence of the lead rendered the supplement adulterated. *Hoffman v. Nutraceutical Corp.*, 2013 WL 2650611, at *4 (D.N.J. June 10, 2013) (Salas, J.).

Likewise, in *Hammer v. Vital Pharmaceuticals, Inc.*, 2012 WL 1018842, at *6 (D.N.J. Mar. 26, 2012) (Wolfson, J.), the theory of liability was based not on an adulteration of the product, but the use of non-natural ingredients without disclosure.

In *Bowman v. RAM Medical, Inc.*, the plaintiff simply alleged that the product was "counterfeit" with nothing more. 2012 WL 1964452, at *1 (D.N.J. May 31, 2012) (Cavanaugh, J.); *id.* at *5 ("Plaintiffs do not supply any supporting facts … rendering the product valueless or unfit."). Although Plaintiffs maintain *Bowman* was wrongly decided, the case is distinguishable because the FAC here alleges in detail the rampant cGMP violations and contamination of the Manufacturer Defendants' MCDs that rendered the products adulterated and illegal to sell.

Finally, *Crozier*, a false advertising case, involving the marketing of a Neosporin-branded antiseptic spray that did not have antibiotics (the claim being that using the Neosporin brand

name was misleading because consumers associate Neosporin with antibiotics) has no application to this set of facts. *See generally Crozier v. Johnson & Johnson Consumer Cos., Inc.*, 901 F. Supp. 2d 494 (D.N.J. 2012) (Simandle, J.).

C. Plaintiffs' FAC Adequately Pleads Implied Warranty Claims Under California and New York Law

Manufacturer Defendants renew their argument that Plaintiffs' implied warranty claims are not viable under California and New York law.

First, Defendants argue that California law requires a showing that the product contains a fundamental defect rendering it not fit for its ordinary use. Manufacturer MTD at 43. But as repeated *ad nauseam* in this brief, Plaintiffs **do** allege, based on *Debernardis* and similar cases, that the adulteration of Defendants' MCDs is a fundamental defect that rendered Defendants' MCDs worthless and completely unfit for their ordinary use. Indeed, Judge Kugler in the closely related *In re Valsartan* litigation agreed that adulteration of pharmaceuticals (including through nitrosamine contamination) renders them economically worthless. *In re Valsartan III*, 2021 WL 222776, at *16 ("This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure.").

Second, Defendants argue that vertical privity is required for Song-Beverly Consumer Warranty claims and implied warranty claims under New York law. Neither statement is correct. California courts have held that the Song-Beverly Act simply does not require privity. *See In re MyFord Touch Consumer Litig.*, 46 F. Supp. 3d 936, 982 (N.D. Cal. 2014) ("For the implied warranty claim under the Song–Beverly Act, there is no privity requirement."); *Ehrlich v. BMW of N. Am., LLC*, 801 F. Supp. 2d 908, 921 (C.D. Cal. 2010) (noting that the "weight of authority" states that "the plain language of section 1792 of the Song–Beverly Act does not impose a …

vertical privity requirement"); *see also* Cal. Civ. Code § 1729 (providing that "every sale of consumer goods that are sold at retail in this state shall be accompanied by the manufacturer's and the retail seller's implied warranty that the goods are merchantable").

Further, California law supplies a privity exception to implied warranty claims where the product at issue is foodstuffs or pharmaceuticals. *Arnold v. Dow Chem. Co.*, 91 Cal. App. 4th 698, 720 (Cal. Ct. App. 2001) ("An exception to the general rule has been recognized in the case of foodstuffs, and has been extended to drugs, on the basis that a drug is intended for human consumption quite as much as is food."); *see also Haley v. Bayer Healthcare Pharm. Inc.*, 2016 WL 10966426, at *3 (C.D. Cal. June 9, 2016) ("California appellate courts have continued to acknowledge the privity exception for breach of implied warranty claims involving prescription drugs.") (internal citations omitted).

New York courts have similarly applied a foodstuffs and pharmaceuticals exception to vertical privity to breach of implied warranty claims. *Addeo v. Metro. Bottling Co.*, 241 N.Y.S.2d 120, 122 (N.Y. App. Div. 1st Dep't 1963) (recognizing implied warranty privity exception when food products or medicines are the subject of the claim).

D. Plaintiffs Adequately Allege Breach Of Express Warranty Claims

The Manufacturer Defendants assert that Plaintiffs' express warranty claims fail under "under each applicable state's laws" because of a supposed failure to identify the warranty language that formed the basis of the bargain. Manufacturer MTD at 45. The FAC more than sufficiently identifies the source of the express warranties made by the Manufacturer Defendants, including the labeling, the product name itself, the patient information leaflets/medication

guides, third-party beneficiary warranties, as well as express warranties detailed elsewhere in the FAC.[22] *See* FAC ¶¶ 280-331.

For instance, Plaintiffs allege that the FDA-approved labeling materials contain express warranties that the Manufacturer Defendants failed to meet with their MCDs (*e.g.*, warranties regarding the sameness of their products to the respective reference listed drugs (RLDs), warranties that the MCDs supplied to and reimbursed by Plaintiffs and Class Members meet the specifications of the Manufacturer Defendants' ANDAs, or warranties regarding the active ingredients of the MCDs). FAC ¶¶ 279-294. In the closely related *In re Valsartan* litigation, Judge Kugler found such materials to constitute express warranties. Specifically, the Court reasoned that

> the [manufacturer's] identification of a generic drug as the chemical equivalent to the Orange Book brand name can do nothing else but constitute an express warranty" and that "[t]he [Manufacturers'] very naming of the drug as valsartan or valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to 'rely' when they were prescribed the drug and bought it as a medication for their high blood pressure … All they had to know was they were buying a generic drug that contained valsartan because the very name 'valsartan' or 'valsartan-containing' constituted itself an express warranty … Put simply, a seller cannot call its product "X" and sell it as "X" and then expect such identification not to create an express warranty that the product is "X." The [manufacturers'] very naming of the drug as valsartan or valsartan-containing amounted to an express warranty on which plaintiffs had no choice but to "rely" when they were prescribed the drug and bought it as a medication for their high blood pressure.

In re Valsartan III, 2021 WL 222776, at *11

The Manufacturer Defendants also argue that the FAC does not adequately allege that any alleged express warranties formed the basis of the bargain, which Defendants contend is a legal requirement in California and New Jersey. On the contrary, Plaintiffs allege certain express

[22] Alternatively, since this is a notice issue raised by the Manufacturer Defendants, Plaintiffs should be allowed to amend to state with specificity the express warranties on which they rely should the Court find notice insufficient.

warranties formed a basis of the bargain for every single purchase of MCDs in California and New Jersey and elsewhere. *In re Valsartan III*, 2021 WL 222776, at *12 ("There was a benefit of the bargain, which arose from the [manufacturers'] identification of the drug as valsartan-containing, which informed plaintiffs the drug was approved as a generic of the Orange Book formulation, upon which plaintiffs relied and acted on in filling their prescriptions for VCDs.").

As set forth above, Manufacturer Defendants provided express warranties in the product labeling, including labeling their products by their generic active ingredient names (*e.g.*, metformin hydrochloride), in the patient information leaflets, on a third-party beneficiary basis, and elsewhere. Those express warranties formed a basis of the bargain for the ultimate consumers of MCDs. The FAC repeatedly alleges that Plaintiffs and Class Members would not have, and could not have, purchased the MCDs but for the express warranties provided by the Manufacturer Defendants in their labeling materials, simply by calling the product metformin or metformin-containing, and through patient information leaflets dispensed with each prescription. *See*, *e.g.*, FAC ¶¶ 279-331. Those allegations are emphasized specifically in the express warranty cause of action for consumer Plaintiffs and Class Members. *Id.* ¶ 459.

Those allegations are plausible because Plaintiffs and Class Members could not have purchased the MCDs but for the express warranties made by Manufacturer Defendants in their labeling, by referring to the products as metformin, and through their patient information leaflet materials. Plaintiffs and Class Members would not have purchased a different drug from what they were prescribed (especially one that contained carcinogenic active ingredients). To the extent the express warranty claims require a basis-for-the-bargain showing, the FAC contains sufficient allegations to plead that element adequately and plausibly.

Even so, reliance (or, as Defendants call it, a "basis of the bargain") is not required in most the jurisdictions for breach of express warranty claims, including in New Jersey and California.

In California, numerous courts have held that reliance is not a requirement for a breach of express warranty claim even where the parties are not in direct privity. *In re Nexus 6P Prod. Liab. Litig.*, 293 F. Supp. 3d 888, 915-16 (N.D. Cal. 2018) (stating that "multiple [courts] have interpreted California law not to require a showing of reliance even if privity is lacking" and reaching same conclusion; *In re MyFord*, 46 F. Supp. 3d at 973 ("[O]ther courts interpreting California law have not found such a limitation—i.e., they have not required reliance where the parties are not in privity."); *McVicar v. Goodman Glob., Inc.*, 1 F. Supp. 3d 1044, 1057 (C.D. Cal. 2014) (in a suit by plaintiffs against a remote air conditioning manufacturer and holding that the express warranty claim was well-pled even though plaintiffs "did not allege that they saw any promises or affirmations of fact prior to purchase"); *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Prac., And Prod. Liab. Litig.*, 754 F. Supp. 2d 1145, 1183 n.22 (C.D. Cal. 2010) (noting that plaintiffs, in a suit against a car manufacturer, "are not required to allege reliance").

New Jersey courts have reached a similar conclusion regarding reliance. *Majdipour v. Jaguar Land Rover N. Am., LLC*, 2013 WL 5574626, at *13 (D.N.J. Oct. 9, 2013) (Walls, J.) (conducting a choice of law analysis on California and New Jersey express warranty law claims, and finding no conflict because "neither privity nor reliance is required in New Jersey" for express warranty claims (citations omitted)); *Elias v. Ungar's Food Prod., Inc.*, 252 F.R.D. 233, 250-51 (D.N.J. 2008) ("To establish a breach of an express warranty … the plaintiff need not prove privity or traditional reliance."); *Bregman Screen & Lumber Co. v. Bechefsky*, 83 A.2d

804, 807 (N.J. App. Div. 1951) ("As a rule, no proof of the buyer's reliance on the warranty is necessary other than that the seller's statements were of a kind which naturally would induce the purchase. The warranty need not be the sole inducement.").

Indeed, most state's case law makes clear reliance/basis of the bargain is not an element of the express warranty claim. *See*, *e.g.*, *In re Gen. Motors Corp. Dex-Cool Prods. Liab. Litig.*, 241 F.R.D. 319-20 (S.D. Ill. 2007) ("It appears that a large number of states in the proposed class, possibly a majority, hold that reliance is not an element of an express warranty claim.") (collecting cases from South Dakota, Florida, Connecticut, Kansas, Alabama, Hawaii, the District of Columbia, New York, Ohio, and Virginia as examples); *see also Lutz Farms v. Asgrow Seed Co.*, 948 F.2d 638, 645 (10th Cir. 1991) ("It appears that the majority of jurisdictions which have addressed the issue have found it unnecessary to require reliance from the buyer before a statement by the seller can be considered an express warranty."); *Barden v. Hurd Millwork Co., Inc.*, 249 F.R.D. 316, 321-22 (E.D. Wis. 2008) (finding reliance/basis for the bargain not required in numerous states including New Jersey). The *General Motors* court also compiled a selection of states where a rebuttable presumption of reliance is created. *In re Gen. Motors Corp. Dex-Cool Prods. Liab. Litig.*, 241 F.R.D. at 320-21 (collecting cases from Illinois, Pennsylvania, Wyoming).

At any rate, reliance is definitively established here, as Judge Kugler found in the closely related *In re Valsartan* case. As found by Judge Kugler, Plaintiffs "had no choice but to 'rely'" on Defendants' express warranties because Defendants could not have imported, distributed, sold, or dispensed adulterated MCDs that were contaminated with nitrosamines, and consequently Plaintiffs could not have purchased those very drugs if they could not have been legally distributed. *In re Valsartan III*, 2021 WL 222776, at *11.

E. Plaintiffs Have Provided Adequate Pre-Suit Notice of Warranty Claims To the Extent Required

Incredibly, Manufacturer Defendants even argue a failure to plead pre-suit notice in the FAC for a number of states for both express and implied warranty claims. But numerous Plaintiffs provided pre-suit notice to some or all defendant groups on a broad enough basis to cover all claims supposedly requiring pre-suit notice. *See generally* Declaration of Andrew J. Obergfell ("Obergfell Decl."). The sufficiency of these letters is a fact question inappropriate for resolution on the pleadings. *In re Valsartan III*, 2021 WL 222776, at *9 ("[P]laintiffs did provide pre-suit notice, even if the Master Complaints did not expressly plead it," and providing leave to amend where necessary "to comply with those requirements").

VI. BREACH OF WARRANTY CLAIMS ARE VIABLE AGAINST RETAIL PHARMACY DEFENDANTS WHO DISPENSE ADULTERATED DRUGS

Even though Retail Pharmacy Defendants profit billions per year from selling prescription medications to consumers (*see*, *e.g.*, FAC. ¶¶ 84-85, 332-335) and—in the case of generic medicines such as the MCDs—actually select the medication to dispense (*id.* ¶¶ 80-82) in nearly all instances, the Retail Pharmacy Defendants argue that they are not merchants or sellers for purposes of warranty claims. This is wrong.

A. Retail Pharmacy Defendants Cite Inapposite Cases All Dealing with Defectively Designed Drugs, Not Defectively Manufactured

The Retail Pharmacy Defendants cite a smattering of cases, but fail to acknowledge a critical issue-dispositive distinction: this case does not involve retailers dispensing a properly-manufactured drug that was later determined to produce harmful side effects but one that was contaminated, non-cGMP compliant, and thus adulterated such as the MCDs here. In *Fagan v. AmerisourceBergen Corporation*, a case cited by the Retail Pharmacy Defendants, the Court found this distinction dispositive in allowing the warranty claims to proceed against retail

pharmacies. 356 F. Supp. 2d 198, 215-16 (E.D.N.Y. 2004) (finding a distinction between the pharmacy "filling a prescription of an adulterated drug" and dispensing "a drug that was later determined to produce harmful side effects" and noting that "[o]ther cases that have dismissed warranty claims also failed to contain evidence that the product was adulterated, misbranded, or otherwise defective … and, thus, are distinguishable from the present case" (collecting cases)).

All the cases cited by the Retail Pharmacy Defendants involve allegations of defectively designed drugs, not adulterated drug at issue. The *Yasmin and Yaz* and *Rezulin* MDL litigations involved allegations of defectively designed oral contraceptives and diabetes medications, respectively. Rezulin was eventually withdrawn from the market because of its inherent design defects. *See also Murphy v. E.R. Squibb & Sons, Inc.*, 710 P. 2d 247, 249 (Cal. 1985) ("The complaint sought damages on the theory of strict liability, alleging that the drug was defectively designed."); *Carrozza v. CVS Pharmacy, Inc.*, 391 F. Supp. 3d 136, 140 (D. Mass. 2019) (plaintiff's claim was based on having an allergic reaction to ingestion of antibiotic Levaquin, not that it was adulterated); *Presto v. Sandoz Pharm. Corp.*, 226 Ga. App. 547, 547 (1997) (plaintiffs' claim was "that defendants are tortiously liable for the suicide of [plaintiffs' son], for failing to warn him of the dangers of discontinuing the use of the drug Clozaril").

This distinction cannot be ignored. While retail pharmacies (and wholesalers) had to purchase and stock the defectively designed branded drugs at issue in the aforementioned design defect cases, here, in this case, Retail Pharmacy Defendants had a wealth of options from whom they could purchase generic metformin, and affirmatively chose to purchase MCDs from Manufacturer Defendants, and affirmatively chose to dispense Manufacturer Defendants' adulterated MCDs to consumers.

The Retailer Defendants' citation to *In re Valsartan* is just as unavailing. Judge Kugler dismissed the express warranty claims against Retailers **with leave to re-plead** facts giving rise to such express warranties. *In re Valsartan III*, 2021 WL 222776, at *22. Plaintiffs in *In re Valsartan* have done just that via a motion for leave to amend (*In re Valsartan*, Case No. 1:19-md-2875, ECF No. 1148 (D.N.J. Apr. 12, 2021)), which the court has yet to rule on.

B. Retail Pharmacy Defendants' Implied Warranties

Implied warranties are most clearly established between consumers/purchasers (including TPPs) of the MCDs and Retail Pharmacy Defendants. There is a direct buyer-seller relationship between consumers who purchase (and TPPs who pay a portion of the purchase price) and retailers who sell them the drug. Direct privity exists in such transactions, as well as the implied warranties that such transactions carry.

The idea behind no-fault implied warranty combined with traditional privity requirements for such claims was to force each buyer to pursue their remedies directly upstream until the ultimate wrongdoer is reached.[23]

It is the lack of fault for implied warranty liability to attach that has led the Retail Pharmacy Defendants to negotiate indemnity agreements and express warranties for the benefit of consumers with the Manufacturer Defendants, whereby the Manufacturer Defendants have agreed to indemnify the Retail Pharmacy Defendants for any liability related to the dispensing of that Manufacturer's drugs, and to make express warranties for the benefit of the ultimate consumers of their drugs. Those agreements exist between all of the Retail Pharmacy Defendants and Manufacturers or Wholesalers in this case. *See*, *e.g.*, FAC ¶ 334.

[23] For the sake of efficiency, many states have since abrogated a need for privity so that the ultimate consumer may sue the wrongdoer directly for economic damages under an implied warranty theory of relief.

The error that underlies Retail Pharmacy Defendants' warranty liability arguments is demonstrated by the unjust outcome that would occur if Manufacturer Defendants indeed are exempt from liability under any particular state's laws simply based on a supposed lack of privity. The law would, in effect, bar an implied warranty claim altogether if a consumer cannot sue the wrongdoer directly (*i.e.*, the manufacturers), but also cannot sue the seller with whom they are in privity (*i.e.*, the retailers). Such an outcome would essentially immunize the entire pharmaceutical supply chain from economic damages liability.

C. Plaintiffs May Pursue Warranty Claims Against The Retail Pharmacies Despite Lack Of Actual Knowledge Of NDMA Contamination

The Retail Pharmacy Defendants put forth an argument that Plaintiffs can only state viable warranty claims if the Retail Pharmacy Defendants had actual knowledge of the contamination, and chose to dispense the MCDs despite that knowledge. In essence, the Retail Pharmacy Defendants are asking the Court to set a standard of liability that equates to willful conduct; anything less and no liability. Not only is the result absurd, it defies the law and would make warranty claims against Retail Pharmacy Defendants untenable under any fact pattern (because knowledge would then raise the conduct to the level an intentional tort as opposed to a breach of warranty).

Predictably, the cases cited do not support the proposition. Of course, Plaintiffs do not demand that Retail Pharmacy Defendants examine and figure out latent design defects of pharmaceutical products. But Plaintiffs do demand (and the law expects) that Retail Pharmacy Defendants source from manufacturers who are fulfilling their own CGMP obligations and to ensure the products are free of manufacturing defects that they then sell and dispense directly to consumers.

VII. PLAINTIFFS HAVE SUFFICIENTLY STATED THEIR FRAUD CLAIMS AGAINST THE MANUFACTURER DEFENDANTS

A. Plaintiffs Plead Fraud With Sufficient Particularity

The Manufacturer Defendants argue Plaintiffs fail to plead their fraud claims with the particularity required by Fed. R. Civ. P. 9(b) because "Plaintiffs' allegations are devoid of specific facts alleging how any Plaintiff was deceived by any Defendant with respect to the alleged NDMA impurities in MCDs." Manufacturer MTD at 49. Not true.

To satisfy Fed. R. Civ. P. 9(b), Plaintiffs' allegations must contain "the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (internal citations and quotations omitted). "As several courts have noted, Rule 9(b)'s heightened standard is somewhat relaxed in a case based on a fraudulent omission, rather than one based on misrepresentation." *Majdipour*, 2013 WL 5574626, at *15 (internal quotations omitted); *Feldman v. Mercedes–Benz USA, LLC*, 2012 WL 6596830, at *10 (D.N.J. Dec.18, 2012) (Martini, J.) ("[P]laintiffs pleading a fraud by omission claim are not required to plead fraud as precisely as they would for a false representation claim."). And "even if the plaintiff does not plead the 'date, place, or time' of the fraud, they may satisfy this heightened standard by injecting precision and some measure of substantiation into their allegations." *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, 2021 WL 307486, at *10 (D.N.J. Jan. 29, 2021) ("*In re Valsartan IV*").

Here, Plaintiffs have sufficiently alleged the "who, what, when, where, and how" necessary to plead a fraud claim:

Who: "The following Defendants manufacture the active pharmaceutical ingredient ('API') for Defendants' MCDs, or are closely affiliated with an entity that does so." FAC ¶ 28; *see also id.* 29-50 (listing Manufacturer Defendants).

What: "At all pertinent times for this action, Defendants represented and warranted to consumers and TPPs that their generic MCDs were therapeutically equivalent to and otherwise the same as the RLD. Specifically, Defendants represented and warranted that the MCDs were fit for their ordinary uses, met the specifications of Defendants' FDA-approved labeling materials, and were manufactured and distributed in accordance with all applicable laws and regulations." FAC ¶ 6. "For years, however, Defendants willfully ignored warnings about the operating standards at several of the overseas manufacturing plants where Defendants' generic MCDs were manufactured for import to the United States, and knowingly and fraudulently manufactured, sold, labeled, marketed, and/or distributed adulterated and/or misbranded MCDs for purchase and reimbursement in the United States by consumers and TPPs." *Id.* ¶ 7. "Defendants' MCDs were adulterated and/or misbranded (and thereby rendered worthless) through contamination with a probable human carcinogen known as N-nitrosodimethylamine ('NDMA') and were otherwise substandard to the Metformin HCL originally approved by the U.S. Food and Drug Administration ('FDA')." *Id.* ¶ 8. *See also id.* ¶¶ 280-331 (alleging distinct representations made by each Manufacturer Defendant); *id.* ¶¶ 173-247 (alleging how each Manufacturer Defendant flouted cGMPs, which caused the contamination of the MCDs).

Where: "[A] plaintiff cannot plead either the specific time of [an] omission or the place." *Cirulli v. Hyundai Motor Co.*, 2009 WL 5788762, at *4 (C.D. Cal. June 12, 2009). However, Plaintiffs do allege "Defendants have manufactured and distributed MCDs throughout the United States, for which plaintiff consumers made co-payments and TPPs, like MSPRC's assignors, paid. MSPRC's assignors made payments for Defendants' drugs in one or more of the following states or territories." FAC ¶ 27; *see also id.* ¶¶ 12-18 (detailing where each Plaintiff resides, which Defendant manufactured their MCD, and which pharmacy Defendant sold them their MCD).

When: "[A] plaintiff cannot plead either the specific time of [an] omission or the place." *Cirulli*, 2009 WL 5788762, at *4. However, Plaintiffs do allege they purchased the MCDs "during the class period." FAC ¶¶ 12-18. Further, in prior complaints, each Plaintiff alleged a more specific timeframe when they purchased the MCDs. *See*, *e.g.*, Case 2:20-cv-02324, ECF No. 1 (Joseph Brzozowski) ¶ 92 (listing MCD purchases from 2009 to 2017); Case No. 2:20-cv-03757, ECF No. 1 (Mohammed Rahman) ¶ 17 (alleging MCD purchases "since 1993"); Case 2:20-cv-04329, ECF No.1 (Stelios Mantalis) ¶ 17 (alleging MCD purchases "since 2011").

How: "The Class Plaintiffs paid for or made reimbursements for generic MCDs that were illegally and willfully introduced into the market by Defendants, which caused them and the millions of other MCD consumers, as well as TPPs, to sustain economic damages. Defendants' generic MCDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs." FAC ¶ 11; *see also id.* ¶¶ 12-18

> (alleging "[h]ad [each] Plaintiff [] known the product was not the same as the RLD, [each] Plaintiff [] would not have paid for these Defendants' MCDs," and that "had Defendants' deception about the impurities within their products been made known earlier, [each] Plaintiff [] would not have paid for these Defendants' MCDs").

Thus, far from failing to allege any factual basis for their fraud claims, the FAC's allegations are more than enough to apprise Manufacturer Defendants of the "who, what, when, where, and how" under Rule 9(b). *In re Valsartan IV*, 2021 WL 307486, at *11 ("These averments are specific enough to satisfy Rule 9(b)'s particularity requirement and put the Manufacturing Defendants on notice of the precise misconduct with which it is charged.").

B. Plaintiffs' Fraud Claims Are Not Time Barred

The Manufacturer Defendants argue that "Plaintiffs' fraud-based claims are also partially or wholly barred by the applicable statutes of limitations." Manufacturer MTD at 50. Not true.

First, Plaintiffs allege their causes of action "accrued on the date the FDA announced the recall of Defendants' generic MCDs." FAC ¶ 337. The FDA began issuing recalls of MCDs in June 2020, and Plaintiffs' original Consolidated Complaint was filed on July 6, 2020. Thus, even under the most restrictive statute of limitations, Plaintiffs' claims would be timely.

Second, provided Plaintiffs' fraud claims accrued before the recalls, the statute of limitations was tolled by the Manufacturer Defendants' fraudulent concealment. Fraudulent concealment "tolls the statute of limitations when an injury or its cause was not known or reasonably knowable despite the exercise of due diligence." *Lomax v. Police Chief of Erie*, 452 F. App'x 83, 84 (3rd Cir. 2011). For a statute of limitations to be tolled due to fraudulent concealment, Plaintiffs must show (1) the Manufacturer Defendants "actively misled [them] respecting [their] claim[s]; (2) the Manufacturer Defendants "prevented [Plaintiffs] from recognizing the validity of the claim within the limitations period; and (3) [Plaintiffs] used

reasonable diligence in uncovering the relevant facts that formed the basis of his claim." *Gunn v. First American Fin. Corp.*, 549 F. App'x 79, 82 (3d Cir. 2013).

Plaintiffs have alleged such facts here. Plaintiffs allege that "no Defendant revealed to the public that their MCDs contained nitrosamines or was otherwise adulterated, misbranded, and/or unapproved, or non-therapeutically equivalent to their RLDs until the FDA's recall announcement in June 2020. The FDA information that preceded the recall announcement is heavily redacted (including the names of the drugs affected by Defendants' respective cGMP violations accounted above), and prior inspection reports or warnings were not fully available to the public, if at all." FAC ¶ 339. Plaintiffs also allege that "each Defendant continued to represent and warrant that their generic MCDs were the same as and therapeutically interchangeable with their RLDs." *Id.* ¶ 340. Thus, no Plaintiff could have discovered through reasonable and ordinarily diligence, each Defendant's deceptive, fraudulent, and unlawful conduct alleged herein." *Id.* ¶ 341. These allegations are sufficient to toll the statute of limitations to either March 2020 (when Valisure released its citizens' petition) or June 2020 (when the FDA began recalling MCDs), in either case making Plaintiffs' claims timely.

Finally, even if Plaintiffs' claims were not tolled, they would still be timely. As the Manufacturer Defendants acknowledge, each Plaintiff alleges how long they purchased MCDs. *See*, *e.g.*, Case 2:20-cv-02324, ECF No. 1 (Joseph Brzozowski) ¶ 92 (listing MCD purchases from 2009 to 2017); Case No. 2:20-cv-03757, ECF No. 1 (Mohammed Rahman) ¶ 17 (alleging MCD purchases "since 1993"); Case 2:20-cv-04329, ECF No. (Stelios Mantalis) ¶ 17 (alleging MCD purchases "since 2011"). The use of the word "since" indicates that Plaintiffs continued to purchase the MCDs—and were therefore continuously deceived by the Manufacturer

Defendants' conduct—up until at least the filing of their original complaint.[24] Such repeated purchases would constitute a "continuing violation," under which the statute of limitations would be tolled until the final purchase of the MCDs. *See*, *e.g.*, *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 385 (D.N.J. 2018) ("Plaintiffs claim to have been overcharged for Effexor XR, as a result of Defendants' settlement agreement. Specifically, from June 2008 through July 2010, Defendants blocked generic extended release venlafaxine from entering the market, which forced consumers to pay a premium for the brand-named drug; thereby, constituting a continuing violation through July 2010."); *Hunter v. Nature's Way Prod., LLC, 2016 WL 4262188*, at *12 (S.D. Cal. Aug. 12, 2016) ("Plaintiff Levin adequately alleges that she relied on misrepresentations Defendants made on their Extra Virgin Coconut Oil and that the misrepresentations constituted a continuing violation over the course of the approximately five years that Plaintiff Levin continued to purchase the Extra Virgin Coconut Oil."); *Capruso v. Village of Kings Point*, 16 N.E.3d 527, 531 (N.Y. 2014) ("In sum, under the continuing wrong doctrine, plaintiffs are able to challenge defendants' ongoing violation of the public trust doctrine at any time while the violation lasts, without being barred by the statute of limitations."); *Whipple v. Taylor University, Inc.*, 162 F. Supp. 3d 815, 834 (N.D. Ind. 2016) ("Whipple contends that he has pleaded a hostile environment claim, is entitled to invoke the continuing violation doctrine due to the recurring nature of the discrimination he alleges he suffered, and the debate about a 180-day limitation period versus a 300-day period is therefore much ado about nothing. The court agrees.").

In short, no matter when Plaintiffs' claims accrued, Plaintiffs' claims are timely.

[24] SINCE, MERRIAM WEBSTER, https://www.merriam-webster.com/dictionary/since ("[F]rom a definite past time **until now**.") (emphasis added).

C. Plaintiffs Sufficiently Allege Knowledge

The Manufacturer Defendants also argue Plaintiffs have "Plaintiffs do not allege any facts plausibly demonstrating that any Defendant actually knew or was recklessly ignorant to alleged nitrosamine 'contamination' in its MCDs." Manufacturer MTD at 52. This argument ignores the myriad allegations in the FAC demonstrating knowledge.

Under Fed. R. Civ. P. 9(b), "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Further, Plaintiffs need not plead an irrefutable fact of scienter "of the 'smoking gun' genre." *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 267 (3d Cir. 2009). Rather, "[p]leading circumstantial grounds for [] knowledge," is enough to meet the Rule 9(b) standard. *Caspersen ex rel. Samuel M.W. Caspersen Dynasty Trust v. Oring*, 441 F. Supp. 3d 23, 40 (D.N.J. 2020); *see also id.* ("The pertinent question is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.").

Here, Plaintiffs allege that "[f]or some time, Defendants have known that generic drugs manufactured overseas, particularly in China and India, were found or suspected to be less safe and effective than their branded equivalents or domestically made generics because of grossly inadequate manufacturing processes, procedures and compliance with cGMPs." FAC ¶ 171. Plaintiffs then bolster this allegation with *hundreds* of paragraphs showing how *each Manufacturer Defendant* has long flouted cGMPs, which resulted in the NDMA contamination of their MCDs that forms the basis for this lawsuit. *See id.* ¶¶ 173-182 (Teva); ¶¶ 183-205 (Emcure/Avet/Heritage/Granules Defendants); ¶¶ 206-213 (Amneal/AvKare Defendants); ¶¶ 214-228 (Aurobindo Defendants); ¶¶ 229-247 (Alkem/Ascend Defendants). Judge Kugler recently found similar allegations to be "sufficient to raise an inference of knowledge or, at the very least, recklessness":

> Plaintiffs here set forth a litany of allegations showing how of each of the Manufacturing Defendants violated cGMPs and then disregarded significant indications of contamination after violating good manufacturing practices. In other words, plaintiffs have alleged a sequence of cause and effect that defendants, had they been even marginally diligent and/or forthright, should have and would have noticed and responded to.
>
> …
>
> Indeed, what makes Plaintiffs[‘] allegations so convincing is that they are required to allege ONLY knowledge generally. Indeed, plaintiffs’ allegations here would meet … a higher standard than that imposed under general common law fraud …. Ultimately … there can be no doubt that plaintiffs have properly pleaded their fraud-based claims against the Manufacturing Defendants in all three Master Complaints.

In re Valsartan IV, 2021 WL 307486, at *12 (rejecting scienter argument); *see also Hall v. Johnson & Johnson*, 2019 WL 7207491, at *25 (D.N.J. Dec. 27, 2019) (“As alleged, Defendants either failed to adequately investigate the potential dangers of the Talc Products, despite its obvious relevance evidenced by the many public inquiries, or Defendants knowingly disseminated false and inaccurate statements as part of a long standing fraudulent scheme. Either scenario is suggestive of scienter.”).

Finally, the Manufacturer Defendants argue “Plaintiffs’ allegations affirmatively concede Defendants’ lack of actual knowledge, asserting that had Defendants adhered to FDA’s guidelines, they ‘would have’ identified or discovered the presence of nitrosamine. The use of the past modal tense (‘would have identified’) signifies that Defendants did not in fact know of the alleged presence of nitrosamines.” Manufacturer MTD at 52 n.19 (citing FAC ¶¶ 265, 269). Judge Kugler recently rejected this *exact* argument:

> [D]efendants argue that plaintiffs’ concede defendants have no knowledge of the contamination when they allege that had defendants adhered to FDA guidelines, they “would have found the NDMA and NDEA contamination almost immediately.” Defendants emphasis on the words “would have found,” ignores the phrase “almost immediately.” Plaintiffs are asserting that defendants never discovered the contamination, only that they would have

> discovered it sooner had they followed FDA guidelines. This allegation does not concede a lack of knowledge, rather it leaves open the possibility that defendants discovered the contamination sometime before the voluntary recalls. Thus, defendants' attempt to squeeze a concession out of the phrase "would have found" falls flat.

In re Valsartan IV, 2021 WL 307486, at *13. So too here. In each quoted portion of the FAC, Plaintiffs here also state that "Defendants would have identified the presence of these nitrosamine contaminants **almost immediately**." FAC ¶ 265 (emphasis added); *see also id.* ¶ 269 ("If these sampling-related and quality-control-related cGMPs were properly observed by Defendants, the nitrosamine contamination in Defendants' MCDs would have been discovered **almost immediately**.") (emphasis added). Thus, this argument is meritless, and the Court should reject it just as Judge Kugler did.

In sum, Plaintiffs' allegations are more than sufficient to allege scienter under Fed. R. Civ. P. 9(b).

VIII. PLAINTIFFS HAVE SUFFICIENTLY ALLEGED EACH OF THEIR STATE CONSUMER PROTECTION LAW CLAIMS AGAINST THE MANUFACTURER DEFENDANTS

A. Plaintiffs Have Stated Claims Under California's Consumer Protection Statutes

The Manufacturer Defendants first argue that Plaintiffs cannot bring claims under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq*., California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500, and California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750, *et seq.*, because "Plaintiffs have not alleged an injury in fact or damages from purchasing and using their MCDs." Manufacturer MTD at 55. This is false. Plaintiffs have alleged economic damages resulting from the purchase of adulterated MCDs.

A plaintiff suffers an injury-in-fact for purposes of the UCL, FAL, and CLRA when he or she has "(1) expended money due to the defendant's acts of unfair competition; (2) lost money or property; or (3) been denied money to which he or she has a cognizable claim." *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 1315 (E.D. Cal. 2014). Here, "the gravamen of Plaintiffs' alleged economic injury is that they did not receive the benefit of their bargain when they purchased Defendants' [M]CDs because they were contrary to Defendants' warranties and representations—that is, the [M]CDs were adulterated, misbranded, non cGMP compliant, unlawful to sell, and therefore essentially worthless." *In re Valsartan II*, 2021 WL 100204, at *8 (sustaining allegations of economic injuries for money paid for NDMA-contaminated medications); *see also* FAC ¶¶ 12-18. These allegations are sufficient for standing under the aforementioned statutes. *Franz*, 745 F. App'x at 48 (holding the plaintiff suffered injury in fact under the UCL where plaintiff alleged "she spent money on a product that should not have been on the market"); *Yachera*, 477 F. Supp. 3d at 1264 ("[T]he absence of allegations that a medication made a plaintiff sick or failed to work as intended is not fatal to establishing injury in fact where, as here, each plaintiff plausibly pleads that she would not have purchased the medication had she known it was defective."); *In re Aqua Dots Prods. Liability Litig.*, 654 F.3d at 751 ("The plaintiffs' loss is financial: they paid more for the toys than they would have, had they known of the risks the beads posed to children. A financial injury creates standing."); *Debernardis*, 942 F.3d at 1086 ("[U]nder a benefit-of-the-bargain theory an economic injury occurs when the purchaser acquires a worthless product, even if there is no indication that she was physically harmed by the product, the product failed to work as intended, or she paid a premium for the product.").

Manufacturer Defendants also argue that Plaintiffs' California claims must "not only satisfy Rule 9(b)'s particularity requirements" because they sound in fraud, "but also must plead actual knowledge of falsity." Manufacturer MTD at 55. Not true. First, Plaintiffs have brought claims under the UCL's proscriptions against "unfair" and "unlawful" conduct. FAC ¶¶ 547, 553. These prongs of the UCL are subject to the more lenient pleading standards of Fed. R. Civ. P. 8. *Castillo v. Seagate Technology, LLC*, 2016 WL 9280242, at *6 n.3 (N.D. Cal. Sept. 14, 2016) ("Plaintiffs' claims under the 'unlawful' and 'unfair' prongs of the UCL are held only to the ordinary pleading requirements of Rule 8."). And even as to Plaintiffs' claims under the "fraudulent" prong of the UCL, the CLRA, and the FAL, "Rule 9(b) requirements may not even be necessary, given that a defendant can violate the UCL, FAL, and CLRA by acting with mere negligence." *Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007, 1020 n.11 (9th Cir. 2020).

Further, even if the more rigid pleading requirements of Rule 9(b) were to apply to Plaintiffs' California claims, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Punian v. Gillette Co.*, 2015 WL 4967535, at *10 (N.D. Cal. Aug. 20, 2015). To this end, Plaintiffs have sufficiently alleged Manufacturer Defendants' knowledge of the NDMA contamination. *See* FAC ¶¶ 173-247 (alleging how each Manufacturer Defendant flouted cGMPs, which caused the contamination of the MCDs); *see also In re Valsartan IV*, 2021 WL 307486, at *12 ("Plaintiffs here set forth a litany of allegations showing how of each of the Manufacturing Defendants violated cGMPs and then disregarded significant indications of contamination after violating good manufacturing practices. In other words, plaintiffs have alleged a sequence of cause and effect that defendants, had they been even marginally diligent and/or forthright, should have and would have noticed and responded to.").

B. Plaintiffs Have Stated Claims Under The Indiana Deceptive Consumer Sales Act

"The IDCSA is a remedial statute designed to provide remedies to consumers [] for practices that the General Assembly deemed deceptive in consumer transactions." *Hoopes v. Gulf Stream Coach, Inc.*, 2014 WL 4829623, at *11 (N.D. Ind. Sept. 29, 2014) (internal citations removed). Under the IDCSA, "[a] deceptive act is actionable if it is either 'uncured' or 'incurable.'" *Id*. An "uncured" act is one:

> (A) with respect to which a consumer who has been damaged by such act has given notice to the supplier under section 5(a) of this chapter; and
>
> (B) either:
>
> > (i) no offer to cure has been made to such consumer within thirty (30) days after such notice; or
> >
> > (ii) the act has not been cured as to such consumer within a reasonable time after the consumer's acceptance of the offer to cure.

Id. (citing Ind. Code § 24-5-0.5-2(a)(7)). "An incurable deceptive act, on the other hand, is one that is done by a supplier as part of a scheme, artifice, or device with intent to defraud or mislead." *Hoopes*, 2014 WL 4829623, at *11 (internal quotations omitted).

Manufacturer Defendants' arguments as to Plaintiffs' claims under the IDCSA are twofold. First, as to "curable" acts under the IDCSA, Manufacturer Defendants argue that Plaintiffs did not give "notice to any Defendant or afforded any Defendant an opportunity to cure" the alleged violation of the IDCSA. Manufacturer MTD at 56. This is wrong. As Plaintiffs noted in their prior Opposition to Defendants' Motion to Dismiss, Plaintiff Wineinger sent a demand letter to Defendants Granules USA, Inc. and Granules Pharmaceuticals, Inc. on March 9, 2020 in compliance with the IDCSA. Ind. Code §§ 24-5-0.5.1, *et seq.*; *see also* ECF No. 95-1; Obergfell Decl., at Ex. A. In this letter, Plaintiff Wineinger stated as follows:

> Granules violated the IDCSA by representing that the metformin medications were of a certain quality or had certain characteristics when they did not, and which information Granules should have known. As a result of Granules' violation of the IDCSA, Ms. Wineinger sustained injury.

ECF No. 95-1, at 2. No offer to cure was made "within thirty (30) days after" notice. Ind. Code § 24-5-0.5-2(a)(7)(B)(i). Further, Plaintiff Wineinger did not bring the IDCSA claim until the original Consolidated Complaint was filed on July 6, 2020, nearly fourth months after the demand letter was sent. Thus, Plaintiffs gave adequate notice to Manufacturer Defendants of their claims under the IDCSA and gave Manufacturer Defendants ample opportunity to cure the violations. *Hoopes*, 2014 WL 4829623, at *12 ("Plaintiffs have submitted evidence that their attorney sent a letter to Gulf Stream's director of consumer affairs on June 15, 2010, which was received by Gulf Stream within a week of that date …. Viewed in the light most favorable to Plaintiffs, although the June 15, 2010, letter and attachments may not state the deceptive acts with exact precision, it was sufficient to put Gulf Stream on notice as required by the IDCSA."); *In re Valsartan III*, 2021 WL 222776, at *9 ("In their opposition, plaintiffs provide copies of pre-suit letters dated before the end of 2018—well before the dates of the Master Complaints—which they had sent to some or all defendant groups …. In examining these letters, the Court finds plaintiffs did provide pre-suit notice, even if the Master Complaints did not expressly plead it.").

Second, as to the "incurable" acts, Manufacturer Defendants argue that Plaintiffs have not "allege[d] any Defendant intended to defraud or mislead them." Manufacturer MTD at 56. But because Plaintiff Wineinger provided notice of the violation of the IDCSA, this argument is not dispositive. *See Hoopes*, 2014 WL 4829623, at *11 ("Intent to defraud or mislead is thus clearly an element of an incurable deceptive act **but is not required to prove an uncured deceptive act**.") (emphasis added, internal quotations removed). Notwithstanding this, Plaintiffs have

alleged an intent to defraud consumers. Specifically, Plaintiffs alleged hundreds of paragraphs showing that Defendants were actively violating cGMPs, despite representing the opposite. FAC ¶¶ 173-247 (alleging how each Manufacturer Defendant flouted cGMPs, which caused the contamination of the MCDs); *id.* ¶¶ 280-331 (alleging distinct representations made by each Manufacturer Defendant); *see also In re Valsartan IV*, 2021 WL 307486, at *12 ("Plaintiffs here set forth a litany of allegations showing how of each of the Manufacturing Defendants violated cGMPs and then disregarded significant indications of contamination after violating good manufacturing practices. In other words, plaintiffs have alleged a sequence of cause and effect that defendants, had they been even marginally diligent and/or forthright, should have and would have noticed and responded to."). Accordingly, Manufacturer Defendants' arguments are meritless.

C. Plaintiffs Have Stated Claims Under the New Jersey Consumer Fraud Act

Manufacturer Defendants argue that Plaintiffs have not alleged an "ascertainable loss of moneys or property" that is necessary for a violation of the NJCFA. Manufacturer MTD at 56. "[T]o state a claim under the NJCFA, a plaintiff must plead (1) an unlawful practice; (2) an ascertainable loss; and (3) a causal relationship between the two." *White v. Samsung Elec. Am., Inc.*, 2019 WL 8886485, at *4 (D.N.J. Aug. 21, 2019) (Arleo, J.) (internal quotations omitted). "Under the NJCFA, an ascertainable loss is either an out of pocket loss or a diminution in value that is not 'hypothetical or illusory' and which is calculable due to the violation." *Id.*, at *3. Plaintiffs need not allege the "exact amount" of the ascertainable loss. *Dicuio v. Brother Intern. Corp.*, 2012 WL 3278917, at *7 (D.N.J. Aug. 9, 2012) ("While these latter plaintiffs do not specify the exact amount that they expended for the color toner cartridges that were not depleted, the exact amount need not be plead in the complaint but can be established by proofs later in the

proceeding."); *Block v. Seneca Mortg. Servicing*, 221 F. Supp. 3d 559, 594 (D.N.J. 2016) ("[P]laintiffs need not plead the exact dollar amount of their loss.").

Plaintiffs here have alleged exactly this type of loss. As noted above, "the gravamen of Plaintiffs' alleged economic injury is that they did not receive the benefit of their bargain when they purchased Defendants' [M]CDs because they were contrary to Defendants' warranties and representations—that is, the [M]CDs were adulterated, misbranded, non cGMP compliant, unlawful to sell, and therefore essentially worthless." *In re Valsartan II*, 2021 WL 100204, at *8; *see also* FAC ¶¶ 12-18. This is more than sufficient for an NJCFA violation. *See*, *e.g.*, *White*, 2019 WL 8886485, at *3 ("Cauley pleads the type of Samsung television, serial number and location of purchase, and further alleges that Samsung was collecting her personal and viewing data, and had it so disclosed, she would not have purchased (or paid substantially less for) the Smart TV. That is sufficient."); *Dicuio*, 2012 WL 3278917, at *8 (sustaining NJCFA claim where "[h]ere, unlike the plaintiffs in Arcand, Plaintiffs have alleged that they incurred out-of-pocket costs as a result of Defendant's misrepresentations as to the need to replace non-exhausted color toner cartridges"); *Jubelt v. United Northern Bankers, Ltd.*, 2015 WL 3970227, at *12 (D.N.J. June 30, 2015) (sustaining NJCFA claim where "Plaintiff has further alleged that United Northern's knowing omissions regarding certain closing fees caused Plaintiff to suffer the alleged loss regarding those fees").

D. Plaintiffs Have Stated Claims Under New York General Business Law §§ 349 and 350

Manufacturer Defendants argue Plaintiffs cannot state GBL §§ 349 and 350 claims because "Plaintiffs did not see the allegedly misleading statements before they purchased the MCDs." Manufacturer MTD at 57. This is not the standard. "Intent to defraud and justifiable reliance by the plaintiff are **not elements of the statutory claim**." *Small v. Lorillard Tobacco*

Co., 94 N.Y.2d 43, 55 (1999) (emphasis added); *see also In re Scotts EZ Seed Litig.*, 304 F.R.D. 397, 409 (S.D.N.Y. 2015) ("[N]either Section 349 nor 350 require proof of reliance, nor proof that defendants intended to mislead consumers.") (internal citations omitted). Indeed, "there is a **presumption of reliance** when the defendant controls the relevant information and a consumer of ordinary intelligence could not discover the true state of affairs." *Guido v. L'Oreal, USA, Inc.*, 284 F.R.D. 468, 483 (C.D. Cal. 2012) (emphasis added). Thus, there is no requirement that Plaintiffs saw or even relied on any of the Manufacturer Defendants' deceptive acts or practices.

Despite the above standard, Plaintiffs *have* alleged they relied on Manufacturer Defendants' misrepresentations and omissions. Specifically, "Plaintiffs allege the Manufacturing Defendants misrepresented that the [M]CDs were therapeutically equivalent to the reference listed drug, complied with cGMPs, were unadulterated, and properly branded." *In re Valsartan IV*, 2021 WL 307486, at *11 (denying motion to dismiss fraud-based claims); *see also* FAC ¶ 12-18 (alleging that each Defendant represented that their generic MCDs were the same as the branded RLD, and Plaintiffs relied on these representations in purchasing their MCDs); *id.* ¶¶ 280-331 (alleging distinct representations made by each Manufacturer Defendant). In addition, Plaintiffs allege "the Manufacturing Defendants failed to disclose that the [M]CDs were not therapeutically equivalent to the reference listed drug, did not comply with cGMPs, were adulterated and improperly branded." *In re Valsartan IV*, 2021 WL 307486, at *11. These allegations are more than sufficient for Plaintiffs' GBL claims. *See*, *e.g.*, *Guido v. L'Oreal, USA, Inc.*, 2013 WL 454861, at *8 (C.D. Cal. Feb. 6, 2013) ("Plaintiffs' allegations successfully state claims under the New York and California consumer protection statutes. Plaintiffs allege that defendants failed to disclose the fact that the Serum was flammable, and this omission was material because, as explained above, if a reasonable consumer using the Serum

knows it is flammable, she will be 'behave differently' if she has reason to believe that she might encounter a source of ignition.").

Manufacturer Defendants also argue Plaintiffs have not "allege[d] an injury" because "New York courts reject the idea that 'consumers who buy a product they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury.'" Manufacturer MTD at 58 (quoting *Small*, 720 N.E.2d at 898). This is not correct. First, New York courts have widely found that "[i]njury is adequately alleged under GBL §§ 349 or 350 by a claim that a plaintiff paid a premium for a product based on defendants' inaccurate representations" or omissions. *Ackerman v. Coca-Cola Co.*, 2010 WL 2925955, at *23 (E.D.N.Y. July 21, 2010); *see also Yourth v. Phusion Projects, LLC*, 2012 WL 13055006, at *5-6 (N.D.N.Y. Sept. 27, 2012) (sustaining price premium theory of injury where defendant failed to disclose that its drink's ingredients "produce[d] dangerous mind-altering effects that are not disclosed on the packaging and labeling or in the marketing, advertising or other promotional materials for Four Loko"); *Tomassini v. FCA US LLC*, 2016 WL 11707888, at *7 (N.D.N.Y. Nov. 23, 2016) ("Plaintiff has pleaded [] actual injur[y] … purchasing the Minivan or paying more for it than he would have had he known of the defect.").

Further, numerous courts have distinguished *Small*. For instance, Judge Rakoff of the Southern District of New York held:

> Defendant's reliance on *Small* … is misplaced. In *Small*, plaintiffs brought suit under Section 349 against cigarette manufacturers, arguing that they would not have purchased the cigarettes had they known they were addictive. However, the plaintiffs in *Small* failed to allege that the cost of cigarettes was affected by the alleged misrepresentation, and therefore pled no injury beyond the deception itself. Here, plaintiffs argue that the product was rendered 'worthless' because of its inherent danger.

In re Amla Litig., 282 F. Supp. 3d 751, 768 (S.D.N.Y. 2017); *see also Fishon v. Peloton Interactive, Inc.*, 2020 WL 6564755, at *11 (S.D.N.Y. Nov. 9, 2020) (Liman, J.) ("*Small* does not stand for the broad proposition that it is legally insufficient for a plaintiff in federal court to plead that it would not have purchased the subject product had it known that defendant's claims were misrepresentations … Unlike in *Small*, in this case, Plaintiffs do allege that they were injured by the misrepresentation—they had access to a smaller number of classes than they reasonably believed they would have access to at the time of purchase.").

In other words, the holding in *Small* is confined to a situation when a consumer's injury does not stem from a company's deceptive conduct. By contrast, Plaintiffs allege the MCDs were worthless *because of* the NDMA contamination (which rendered the MCDs unsafe and unsuitable for use), and Plaintiffs would not have purchased the MCDs had they known of the NDMA contamination. FAC ¶¶ 12-18, 572, 584. As a result, "there is a connection between the misrepresentation and [] harm from, or failure of, the product," and Plaintiffs have stated an actionable injury under GBL §§ 349 and 350. *Fishon*, 2020 WL 6564755, at *11.[25]

IX. PLAINTIFFS ADEQUATELY PLEAD THEIR FRAUD AND STATE CONSUMER PROTECTION CLAIMS AGAINST THE RETAIL PHARMACY DEFENDANTS

A. Plaintiffs Adequately Plead Each Element Of Their Fraud Claim

The Retail Pharmacy Defendants argue that "[f]or the reasons stated in the Manufacturers' brief at Section II.H and adopted herein, Plaintiffs fail to articulate any type of fraud against any Defendant, much less the Pharmacies." Pharmacy MTD at 35. That is wrong.

[25] *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009), is likewise distinguishable. In that case, "plaintiff ma[de] no reference to specific acts, representations and/or omissions that she claims are deceptive nor does she allege why these acts were deceptive." *Horowitz*, 613 F. Supp. 2d at 287. By contrast, Plaintiffs here have alleged specific material misrepresentations and omissions by Defendants—the representation that the generic MCDs were equivalent to the RLDs, and the failure to disclose that the MCDs were contaminated with NDMA—that harmed Plaintiffs vis-à-vis the purchase price of their MCDs. FAC ¶¶ 12-18.

For the reasons set forth in Argument § VII.A, *supra*, Plaintiffs plausibly plead their fraud claim against the Manufacturer Defendants, and satisfy the requirements of Rule 9(b). The same is true for the Retail Pharmacy Defendants.

To prevail on a claim of common law fraud in New Jersey, Plaintiffs must show that Defendants: "(1) made a representation or omission of a material fact; (2) with knowledge of its falsity; (3) intending that the representation or omission be relied upon; (4) which resulted in reasonable reliance; and that (5) plaintiff suffered damages." *DepoLink Ct. Reporting & Litig. Support Servs. v. Rochman*, 64 A.3d 579, 586 (N.J. App. Div. 2013). Other state's laws require identical elements. *See, e.g.*, *DeAngelis v. Corzine*, 17 F. Supp. 3d 270, 280-81 (S.D.N.Y. 2014) ("The elements of common law fraud under New York law are: (1) a material representation or omission of fact; (2) made with knowledge of its falsity; (3) with scienter or an intent to defraud; (4) upon which the plaintiff reasonably relied; and (5) such reliance caused damage to the plaintiff."); *RD & J Properties v. Lauralea-Dilton Enterprises, LLC*, 165 N.C. App. 737, 744-45 (N.C. Ct. App. 2004) ("The essential elements of actionable fraud are: (1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party."); *Probir K. Bondyopadhyay, et al., v. The Bank of New York Mellon,* 2020 WL 4676765, at *4 (S.D. Tex. Aug. 11, 2020) ("The Texas Supreme Court has held that '[a] fraud cause of action requires 'a material misrepresentation, which was false, and which was either known to be false when made or was asserted without knowledge of its truth, which was intended to be acted upon, which was relied upon, and which caused injury.'") (quoting *Formosa Plastics Corp. v. Presidio Eng'rs & Contractors, Inc.*, 960 S.W.2d 41, 47-48 (Tex. 1998)).

Here, each Retail Pharmacy Defendant sold MCDs by representing them as therapeutically equivalent or the same as metformin, and further represented that the MCDs complied with cGMPs. *See, e.g.*, FAC ¶¶ 171-271; *see also id.* at ¶¶ 332-335 (describing Retail Pharmacy Defendants' representations and omissions regarding the nature of the MCDs). Each Retail Pharmacy Defendant omitted the material fact that their MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved. *See, e.g.*, *id.* at ¶¶ 279-335, 415-416; *see, e.g.*, *In re Propulsid Prods. Liab. Litig.*, 2001 WL 1446714, at *2 (E.D. La. July 2, 2002) (denying motion to dismiss fraudulent and negligent misrepresentation claims against pharmacies). Plaintiffs further allege that the Retail Pharmacy Defendants "knew, or reasonably should have known, that their misrepresentations were materially false or misleading, or that the omission of material facts rendered such representations false or misleading."[26] FAC at ¶ 418. The Retail Pharmacy Defendants "knew, or had reason to know, that their misrepresentations and omissions would induce Class members to pay for some or all of the cost of Defendants' MCDs." *Id.* at ¶ 419. Plaintiffs allege that they in fact relied on the Retail Pharmacy Defendant's misrepresentation and omissions and suffered damage as a result of their reliance thereon (*i.e.*, they spent money on a product they would not have purchased had they known it contained NDMA and was adulterated). *Id.* at ¶¶ 417, 423, 425. As such, Plaintiffs adequately plead each element of their fraud claim against the Retail Pharmacy Defendants.

[26] Rule 9(b) permits allegations of knowledge to be alleged generally. *See Marangos v. Swett*, 341 F. App'x 752, 757 (3d Cir. 2009) ("Rule 9(b) requires particularity when pleading fraud, but it allows factual matter concerning malice, intent, and knowledge, to be alleged generally under the less-than-rigid – though still operative – strictures of Rule 8.").

B. Plaintiffs Plead Their Fraud Claim With Sufficient Particularity As To The Retail Pharmacy Defendants

The Retail Pharmacy Defendants further argue that "Plaintiffs' allegations fail to identify any particular details of the alleged fraud—no time, place, content of any statement or misrepresentation by the Pharmacies as may relate to any individual Plaintiff's purported purchase of metformin—and do not inject precision or a measure of substantiation into their allegations." Pharmacy MTD at 36-37. That is wrong.

Much like their allegations directed toward the Manufacturer Defendants, Plaintiffs plead "the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (internal citations and quotations omitted). This is especially true given the more relaxed standard where, as here, the case is based on a fraudulent omission. *Majdipour*, 2013 WL 5574626, at *15 (internal quotations omitted). Here, Plaintiffs have sufficiently alleged the "who, what, when, where, and how" necessary to plead a fraud claim against the Retail Pharmacy Defendants:

Who: "Retail pharmacies have supply arrangements with manufacturers. They stand in direct contractual privity with consumers, given that retail pharmacies (be they brick-and-mortar or mail-order) are the entities that dispensed and received payment for the adulterated and/or misbranded MCDs for which consumers paid and TPPs reimbursed." FAC ¶ 51; *see also id.* at ¶¶ 51-71 (listing Retail Pharmacy Defendants and identifying each one's role in the fraudulent scheme, namely selling "adulterated and/or misbranded MCDs to U.S. consumers and TPPs across the country during the class period").

What: "By selling pharmaceutical prescription drugs in the stream of commerce, each retail pharmacy defendant warrants that the generic drugs for which they receive payments from are the same as existing brand-named drugs in active ingredient, dosage form, safety, strength, methods of administration, quality, and performance characteristics. More generally, retail pharmacy defendants warrant that prescription drugs they sell are of a standard quality." FAC ¶ 333. "Defendants' MCDs were adulterated and/or misbranded (and thereby rendered worthless) through contamination with a probable human carcinogen known as N-nitrosodimethylamine ("NDMA") and were otherwise substandard to the

Metformin HCL originally approved by the U.S. Food and Drug Administration ("FDA")." *Id.* ¶ 8. *See also id.* ¶¶ 332-335 (alleging distinct representations and omissions made by each Retail Pharmacy Defendant regarding product quality and safety).

Where: "[A] plaintiff cannot plead either the specific time of [an] omission or the place." *Cirulli*, 2009 WL 5788762, at *4. However, Plaintiffs do allege "[r]etail pharmacies are where consumers purchase and fill prescriptions for pharmaceuticals. As a result, retail pharmacies and consumers have direct privity of contract. With each sale of prescription drugs, retail pharmacies impliedly warrant to consumers that the prescription drugs being sold to them are merchantable and/or fit for its ordinary uses," FAC ¶ 332, suggesting that the misrepresentations and omissions were made at the point of sale; *see also id.* ¶¶ 12-18 (detailing where each Plaintiff resides and which Retail Pharmacy Defendant sold them their MCD).

When: "[A] plaintiff cannot plead either the specific time of [an] omission or the place." *Cirulli*, 2009 WL 5788762, at *4. However, Plaintiffs do allege they purchased the MCDs "during the class period." FAC ¶¶ 12-18. Further, in prior complaints, each Plaintiff alleged a more specific timeframe when they purchased the MCDs. *See, e.g.*, Case 2:20-cv-02324, ECF No. 1 (Joseph Brzozowski) ¶ 92 (listing MCD purchases from 2009 to 2017); Case No. 2:20-cv-03757, ECF No. 1 (Mohammed Rahman) ¶ 17 (alleging MCD purchases "since 1993"); Case 2:20-cv-04329, ECF No. 1 (Stelios Mantalis) ¶ 17 (alleging MCD purchases "since 2011").

How: "The Class Plaintiffs paid for or made reimbursements for generic MCDs that were illegally and willfully introduced into the market by Defendants, which caused them and the millions of other MCD consumers, as well as TPPs, to sustain economic damages. Defendants' generic MCDs were not fit for their ordinary use and Defendants have been unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs." FAC ¶ 11; *see also id.* ¶¶ 12-18 (alleging "[h]ad [each] Plaintiff [] known the product was not the same as the RLD, [each] Plaintiff [] would not have paid for these Defendants' MCDs," and that "had Defendants' deception about the impurities within their products been made known earlier, [each] Plaintiff [] would not have paid for these Defendants' MCDs").

Thus, Plaintiffs more than adequately meet the requirements of Rule 9(b).

The Retail Pharmacy Defendants persist that "[t]o the extent Plaintiffs attempt to articulate actual activity or misrepresentations that form the basis of their claims, they do so with vague and conclusory statements regarding all 'Defendants,' without differentiation as to the roles or actions of any specific entity in the supply chain, such that the allegations are

indistinguishable and fail to put each of the Defendants on notice of the roles they played in any allegedly fraudulent scheme." Pharmacy MTD at 35. That is wrong. As explained above, Plaintiffs identify the role of each actor in the supply chain, including the Retail Pharmacy Defendants, and set forth the particular representations and material omissions made by the Retail Pharmacy Defendants. Therefore, Plaintiffs' allegations are more than sufficient to place the Retail Pharmacy Defendants "on notice of the precise misconduct" alleged. *Nationstar Mortg., LLC v. Baronfeld*, 2014 WL 5361890, at *3 (D.N.J. Oct. 21, 2014).

C. Plaintiffs Adequately State Claims Under State Consumer-Protection Statutes Against The Pharmacy Defendants

The Retail Pharmacy Defendants argue that "[i]n addition to the numerous pleading deficiencies of Plaintiffs' state law consumer protection claims, as articulated in the Manufacturers' brief at Section II.H, Plaintiffs' claims also fail because the Pharmacies' act of dispensing prescription medication is not a 'consumer-oriented practice.'" Pharmacy MTD at 37. For the reasons set forth in Argument § VIII, *supra*, Plaintiffs plausibly plead their claims under the various consumer-protection laws as to the Manufacturer Defendants. Further, the Retail Pharmacy Defendants' argument that dispensing MCDs contaminated with NDMA to consumers is not a "consumer-oriented practice" is wrong.

The Retail Pharmacy Defendants' material omissions regarding the NDMA contamination were "part and parcel of defendant's efforts to sell its [products] … to prospective [consumers]." *Gomez-Jimenez v. New York Law Sch.*, 103 A.D.3d 54, 58 (N.Y. App. Div. 1st Dep't 2012); *Oswego Laboreers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 25 (1995) (Plaintiff need only "demonstrate that the acts or practices have a broader impact on consumers at large"). While metformin is a prescription medication, a consumer still has a choice in determining which medication to purchase. There are numerous manufacturers

of generic metformin, and not all manufacturers produced MCDs contaminated with NDMA. Had the Retail Pharmacy Defendants not engaged in material omissions, and properly informed Plaintiffs about the true nature of the MCDs and the availability of a non-contaminated alternative, Plaintiffs and class members would not have purchased the contaminated MCDs and instead would have purchased a safe alternative. This is doubly true because if the true nature of the contaminated MCDs were disclosed, they would not even be on the market because it is illegal to sell MCDs contaminated with NDMA beyond FDA limits. *See*, *e.g.*, FAC ¶ 417 ("Plaintiffs and other Class Members would not have purchased Defendants' MCDs had they known the truth. Indeed, Plaintiffs and other Class Members could not have paid for Defendants' MCDs had they known the truth because Defendants' MCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to Plaintiffs and Class Members based on Defendants' fraudulent misrepresentations and omissions.").

The Retail Pharmacy Defendants argue that "Plaintiffs' consumer protection claims against the Pharmacies represent a dramatic and unprecedented form of liability." Pharmacy MTD at 38. On the contrary, retailers who sell fraudulently mislabeled products to consumers may be liable for their own actions or inactions. *See*, *e.g.*, *In re Propulsid Prods. Liab. Litig.*, 2002 WL 1446714, at *3 (E.D. La. July 2, 2002) (denying motion to dismiss fraudulent and negligent misrepresentation claims against pharmacies); *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 335-339 (D.N.J. 2014) (McNulty, J.) (refusing to dismiss, *inter alia*, California and New Jersey consumer protection claims against manufacturer and retailers from whom consumers purchased washing machines). Here, the Retail Pharmacy Defendants sold MCDs by representing them as therapeutically equivalent or the same as metformin, and by representing that they complied with cGMPs. *See*, *e.g.*, FAC ¶¶ 332-335. The Retail Pharmacy Defendants

omitted the material fact that their MCDs were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved. *See*, *e.g.*, FAC ¶ 470.

Accordingly, Plaintiffs adequately state their state consumer-protection claims against the Retail Pharmacy Defendants.

X. PLAINTIFFS PLEAD COGNIZABLE NEGLIGENCE AND NEGLIGENCE *PER SE* CLAIMS

It is without doubt that Plaintiffs cognizably plead conduct which would give rise to state law negligence and negligence *per se* claims against the Defendants. The FAC includes detailed allegations about the Manufacturer Defendants' duties to manufacture a drug that is of the safety and purity it purported to be, their duties to manufacture a generic drug that is the "same" as the RLD (FAC ¶¶ 115-116; 122-125), their duty to maintain manufacturing facilities that were complying with all applicable good Manufacturing Practices standards (*id.* ¶¶ 117-121; 134-137), and their duty to maintain quality assurance functioning to safeguard against the manufacture of adulterated products (*id.* ¶¶ 138-141). Plaintiffs similarly included detailed allegations as to the Retail Pharmacy Defendants' duties to investigate potentially illegitimate product (*id.* ¶¶ 91-96; 335). Plaintiffs then, in painstaking detail, allege how Defendants breached those duties. *See*, *e.g.*, *id.* ¶¶ 171-182 (Teva); ¶¶ 183-213 (Emcure/Heritage/Granules); ¶¶ 214-228 (Aurobindo); ¶¶ 229-247 (Alkem); ¶¶ 332-335; ¶¶ 489-498 (Pharmacy Defendants).

A. Defendants' Arguments About the Veracity of Plaintiffs' Allegations Are Improper

Rather than arguing about the sufficiency of the allegations to give rise to a cognizable claim, Defendants instead ask that the Court improperly look beyond the four corners of Plaintiffs' well-pleaded complaint and make factual determinations about the veracity and

truthfulness of Plaintiffs allegations. In inviting the Court to make factual determinations about whether a particular product "worked as intended" and "controlled [Plaintiffs] blood sugar," Defendants have essentially converted their Motion to Dismiss into a Motion for Summary Judgment, in a case without an iota of discovery. This is improper.

Indeed, it is not for the Court at 12(b)(6) to determine the probability that a Plaintiff will ultimately succeed in their claims, but rather to assess whether the Plaintiff has plausibly delineated a claim within the four corners of their complaint. *In re Lipitor Antitrust Litig.,* 868 F.3d 231, 260 (3d Cir. 2017); *see also Twombly*, 550 U.S. at 570. It is also not Plaintiffs' obligation, in drafting their complaint, to "plead facts that, if true, definitely rule out all possible innocent explanations." *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014).

Here, Plaintiffs have alleged that they purchased a product warranted as being the same as the RLD Product. Plaintiffs allege that this product was different from RLD Product because these products contained a known human carcinogen, NDMA, which the RLD did not. Plaintiffs allege that because these products were different from the RLD, and were, in fact, adulterated and misbranded, these products purchased by Plaintiffs were worthless. FAC ¶¶ 277-278; *see also id.* ¶¶ 290-291. Plaintiffs also alleged that had they known the product was not the same as the RLD and contained NDMA, they alleged that they would not have purchased the product. *Id.* ¶ 366. Plaintiffs alleged that because of the conduct of the Defendants, they were injured. *Id.* ¶ 498. To invite the Court to probe further into these allegations and make determinations of whether they were really injured is not only an improper exercise for the 12(b)(6) exercise, but it also serves to show why these claims must proceed and be subject to full discovery.

B. Determining Whether the Economic Loss Doctrine Applies Requires Full Discovery

The Defendants also argue that the economic loss doctrine would preclude a negligence claim for economic losses. But Defendants side-step the fact that most states have exceptions to the economic loss rule for negligence claims. For example, California has recognized an exception to the economic loss doctrine where a "special relationship" exists between the parties, or an independent duty is present. *See*, *e.g.*, *Robinson Helicopter, Inc. v. Dana Corp.,* 102 P.3d 1256 (Cal. 2004); *Erlich v. Menezes,* 21 Cal. 4th 543, 550 (1999). New York has likewise recognized an exception to the Economic Loss Doctrine when an independent duty is present. *See In re Facebook Inc., IPO Sec. & Derivative Litig*., 986 F. Supp. 2d 428 (S.D.N.Y.2013). These fact-based exceptions include questions such as the existence of a special relationship, the existence of independent duties, exceptions regarding public safety, and special circumstances which require a reallocation of risk, and where the economic loss was caused by a negligent misrepresentation by the Defendant in the business of supplying information for the guidance of others in business transactions. *In re Target Corp. Data Sec. Breach Litig.*, 66 F. Supp. 3d 1154, 1173 (D. Minn. 2014) (collecting cases from various stats).

Each of these questions about whether Plaintiffs' economic loss claims would fall into one of the many delineated exceptions articulated by states which have an economic loss rule for negligence claims are intensive factual determinations which make dismissal premature at the 12(b)(6) stage. *Id.*

C. The Retail Pharmacy Defendants Are Not Entitled to Special Treatment

The Retail Pharmacy Defendants boldly argue that Pharmacies cannot be found negligent unless they are found to be "professionally negligent in a malpractice type action." Pharmacy MTD at 27. Then, in what appears to be an undercutting of their own bright line rule regarding

"professional negligence," the Pharmacy Defendants argue that there while might be some duties they are required to uphold beyond those in a "malpractice type action," those duties do not include a "duty to test."

As a primary threshold, the Retail Pharmacy Defendants have a duty to take proper care when filling sourcing their prescription drug products and filling a customer's prescription. *See*, *e.g.*, *Arrington v. Walgreen Co.*, 664 F. Supp. 2d 1230, 1233 (M.D. Fla. 2009) (under Florida law, pharmacy may be liable for negligence for failure to use due and proper care in filling prescriptions, even if prescription is filled in accordance with physician's instructions).

For instance, in *Arrington*, Walgreens argued it was not liable for dispensing a drug at all. The court rejected this notion and denied Walgreens' motion to dismiss:

> Walgreens would have this Court interpret a pharmacist's duty to use "due and proper care in filling the prescription" as being satisfied by a robotic compliance with the instructions of the prescribing physician. In Walgreens' view, so long as the paperwork is in order, and so long as the drug going out the door matches the drug prescribed, the pharmacist (and, by extension, Walgreens) cannot face liability. However, none of the cases cited by Walgreens go this far. And though the law in this area is far from settled, two Florida Courts of Appeal have rejected this contention.

Arrington, 664 F. Supp. 2d at 1232-33. The Retail Pharmacy Defendants would have this Court adopt the same "robotic compliance" argument which failed before. That is, if a physician writes prescription for a particular generic drug, the Pharmacy Defendants are immune from any liability because they mechanically followed the physician's prescription and did not commit "professional malpractice" in doing so.

This Court should reject this unduly narrow argument, as did the *Arrington* court. *See*, *e.g.*, *In re Welspun Litig.*, 2019 WL 2174089, at *19 (S.D.N.Y. May 20, 2019) (denying in part motion to dismiss filed by retailers who were alleged to have sold falsely labeled bed linens); *Kurtz v. Kimberly-Clark Corp.*, 321 F.R.D. 482, 554 (E.D.N.Y. 2017) (certifying class claims

against manufacturers and retailers for selling falsely labeled 'flushable' moist toilet wipes); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 212-13 (E.D.N.Y. 2004) (consumer stated negligence claim against distributor and pharmacy for sale of counterfeit drugs); *Dunn v. Kanawha Cnty. Bd. Educ.*, 459 S.E.2d 151, 157 (W. Va. 1995) (all entities in chain of distribution may be liable under negligence theory).

1. Innocent Seller Exceptions Require Full Discovery and Cannot Be Disposed of During Rule 12(b)(6) Briefing

As one last final attempt, the Retail Pharmacy Defendants argue that they are not liable under certain states' innocent seller provisions. As much as the Retail Pharmacy Defendants wish to depict the law as being uniform in absolving them from liability, the reality is far from that. While it is true that some states have enacted statutes limiting strict liability to innocent sellers, the FAC alleges the Pharmacy Defendants knew or should have known of the defect and yet did nothing. Moreover, most innocent seller statutes include exceptions permitting liability to attach such as where the manufacturer of the product cannot be identified, where there are jurisdictional issues, or where there may be potential insolvency of other defendants or an inability to collect a judgment.[27]

While the Retail Pharmacy Defendants try to invite the Court to make the factual determinations needed in order to understand whether an innocent seller defense will apply, it is improper to rule on these defenses in absence of full discovery. *See*, *e.g.*, *Thomas v. Firerock Prods., LLC*, 40 F. Supp. 3d 783, 792 (N.D. Miss. 2014) (denying motion to dismiss on basis of

[27] *See*, *e.g.*, Ala. Code § 6–5–521(c); *see also, e.g.,* D.C.A. tit. 18 §7001 (Delaware); Ind. Code § 34-20-2-4; Iowa Code Ann. § 613.18; Kansas Stat. 60-3306 (Kansas); KRS 411.340 (Kentucky); Md. Code Ann., Cts. & Jud. Proc. § 5-405; Minn. Stat. § 544.41 (Minnesota); Mo. Ann. Stat. § 537.762 (Missouri); N.J. Stat. § 2A:58C-2 (New Jersey); N.C.G.S.A. § 99B-2(a) (North Carolina); N.D. Cent. Code § 28-01.3-04 (North Dakota); O.R.C. 2307.78(B) (Ohio); Okla. Stat. tit. 76, § 52.2.E (Oklahoma); Tenn. Code Ann. §29-28-106 (Tennessee); Texas CPRC Sec. 82.003(a)(7); Wis. Stat. § 895.047 (Wisconsin).

innocent seller affirmative defense because elements not met on face of complaint); *Fahy v. Taser Int'l, Inc.*, 2010 WL 559249, at *2 (E.D. Mo. Feb. 10, 2020) (Missouri's innocent seller statute "does not affect a defendant's potential liability to a plaintiff at the pleadings stage"); *Geraczynski v. National R. R. Passenger Corp*, 2013 WL 5934552, at *4 (D.N.J. Nov. 1, 2013) (only ruling on innocent seller defense at summary judgment after discovery). As Judge Kugler held in *In re Valsartan IV*, there are "numerous exceptions or prerequisites for immunity," and courts "overwhelmingly" address the merits of that defense at the summary judgment stage. 2021 WL 307486, at *21-22.

XI. PLAINTIFFS' UNJUST ENRICHMENT CLAIMS SHOULD NOT BE DISMISSED

A. Plaintiffs' Unjust Enrichment Claims Are Properly Pled

Defendants argue that Plaintiffs' unjust enrichment claims fail to satisfy the pleading requirements of Fed. R. Civ. P. 8(a) because they consist of only a formulaic recitation of the elements and group pleading. Manufacturer MTD at 61-62; Pharmacy MTD at 49. In fact, Plaintiffs state facially plausible claims for unjust enrichment by setting out the factual basis for Defendants' liability and organizing Defendants by their distribution level.

In the FAC, Plaintiffs include factual matter to support each element of their unjust enrichment claims.[28] Plaintiffs first allege that the Manufacturer Defendants manufactured and distributed MCDs for the United States market that were dispensed directly to consumers by the Pharmacy Defendants as part of an interconnected drug supply chain, allowing both the Manufacturing and Pharmacy Defendants to amass significant profits from the sale of MCDs to

[28] A claim for unjust enrichment requires three elements: (1) receipt of a benefit; (2) unjust retention of the benefit; (3) at the expense of another. RESTATEMENT (3D) OF RESTITUTION AND UNJUST ENRICHMENT § 1 (2011); *see also Peterson v. Cellco P'ship*, 164 Cal. App. 4th 1583, 1593 (Cal. Ct. App. 2008); *Neibert v. Perdomo*, 54 N.E.3d 1046, 1051 (In. Ct. App. 2016); *VRG Corp. v. GKN Realty Corp.*, 641 A.2d 519, 554 (N.J. 1994); *EJ Brooks Co. v. Cambridge Sec'y Seals*, 105 N.E.3d 301, 312 (N.Y. 2018).

Plaintiffs. FAC ¶¶ 11, 51, 79, 84, 479-80, 485-86. Plaintiffs next allege that it would be unjust for Defendants to retain the benefits because the MCDs they paid for were adulterated through contamination with NDMA; as a result, the drugs Plaintiffs received were different from the drugs they sought to pay for and, further manufacture, sale, and introduction of those adulterated drugs into the U.S. market was unlawful. *Id.* ¶¶ 1, 6, 8, 11, 134, 142-47, 479-80, 485-87. Finally, Plaintiffs allege that the benefit was retained at their expense because they directly paid for or made reimbursements for adulterated MCDs believed to be Metformin. FAC ¶¶ 11, 51, 481, 487. Moreover, Plaintiffs did not engage in impermissible group pleading; to the extent the allegations pertaining to unjust enrichment are made against "Defendants," the "Manufacturing Defendants," or the "Retail Pharmacy Defendants," Plaintiffs explained that such organization was for purposes of clarity only. *Id.* ¶¶ 28–75. Plaintiffs identified each Defendant, its role, and the distribution level at which it primarily operates such that one needs only to identify which category to which a particular Defendant belongs to determine which allegations are made against that Defendant. *Id.*

The FAC does not simply recite the elements of unjust enrichment in the form of conclusory allegations but, rather, states the factual basis showing how both sets of Defendants came to profit from the manufacture and sale of MCDs and the reason that it would be unjust to allow Defendants to retain profits obtained through illegal distribution and sale of adulterated drugs. Further, the claims against each individual Defendant can "readily be extracted" by reviewing the distribution category to which it has been assigned. *See Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 386 (D.N.J. 2019) (explaining that impermissible group pleading occurred where it was unclear which defendants were manufacturers and which were distributors). Therefore, the facts alleged by Plaintiffs are enough to allow the court to draw a reasonable

inference of both the Manufacturing and Pharmacy Defendants' liability. *Iqbal*, 5556 U.S. at 678.

B. The Existence of an "Adequate Remedy at Law" Does Not Preclude Plaintiffs' Unjust Enrichment Claims

1. Plaintiffs Do Not Have an Adequate Remedy at Law

Defendants argue that Plaintiffs' unjust enrichment claims should be dismissed because Plaintiffs' other claims for monetary damages constitute an adequate remedy at law. This argument fails because it ignores the different harms that Plaintiffs' unjust enrichment and monetary damages claims seek to redress. An "adequate remedy at law" is a "legal remedy (such as an award of damages) that provides sufficient relief to the petitioning party, thus preventing the party from obtaining equitable relief." REMEDY, BLACK'S LAW DICTIONARY (11th Ed. 2019). However, "[t]he availability of some legal remedy does not mean such a remedy is adequate." *TD Bank N.A. v. Hill*, 928 F.3d 259, 283 (3d. Cir. 2019) (noting, for purposes of an injunction involving copyright infringement, that not all copyright infringement could be remedied by damages). In the Third Circuit, parties "routinely seek both money damages and equitable relief arising from the same allegedly wrongful conduct" but, "[i]n many cases, prayed-for monetary and equitable relief will serve entirely distinct remedial purposes." *In re Ben Franklin Hotel Assoc.*, 186 F.3d 301, 306 (3d Cir. 1999). For example, in *Ben Franklin*, the court refused to consider money damages an adequate substitute for equitable relief, where the equitable relief sought was reinstatement in a partnership, because even though reinstatement would provide access to lost profits, they were different from damages. *Id.* at 307-08.

Here Plaintiffs' unjust enrichment claim seeks to redress different harms than their claims for monetary damages. Plaintiffs' claims for monetary damages seek reimbursement for the MCDs they purchased, their replacement costs, and the harm to Plaintiffs as consumers and

victims of negligence. FAC ¶¶ 357-476, 489-585. By contrast, Plaintiffs' unjust enrichment claims seek to redress the harm caused by Defendants amassing profits through the illegal sale of adulterated and/or misbranded MCDs that were contaminated with a probable human carcinogen. *Id.* ¶¶ 482, 488. In seeking disgorgement of profits, Plaintiffs' unjust enrichment claims seeks to prevent Defendants from profiting from their wrongdoing—which Plaintiffs' remaining claims cannot accomplish. *See* RESTATEMENT (3D) OF RESTITUTION AND UNJUST ENRICHMENT § 51(e) (2011) ("The object of the disgorgement remedy—to eliminate the possibility of profit from conscious wrongdoing—is one of the cornerstones of the law of restitution and unjust enrichment."). Plaintiffs do not have an adequate remedy at law because their claims for monetary damages are not an "adequate substitute" for their unjust enrichment claims.

2. Alternate Pleading Rules Permit Plaintiffs to Plead Unjust Enrichment and Legal Claims at the Pleadings Stage

Even assuming the existence of an adequate remedy at law, dismissal of Plaintiffs' unjust enrichment claims at this stage is premature because Plaintiffs may plead alternative or inconsistent claims. A "party may set out two or more statements of a claim or defense alternatively or hypothetically" and "may state as many separate claims or defenses as it has regardless of consistency." Fed. R. Civ. P. 8(d)(2)-(3). Parties who would ordinarily face an election of remedies are not precluded from pleading those theories, but simply face "an election of theory on which the plaintiff will proceed at trial." *Murray v. Fairbanks Morse*, 610 F.2d 149, 164 n.17 (3d Cir. 1979). Thus, "legal and equitable grounds may be pled alternatively, or even inconsistently." *Torsiello v. Strobeck*, 955 F. Supp. 2d 300, 312 n.6 (D.N.J. 2013).

In an analogous case, Judge Greenaway of this District denied a motion to dismiss an unjust enrichment claim despite the existence of an adequate remedy at law, reasoning that "it would be premature at this stage of the proceedings" because the plaintiffs were entitled to plead

alternate theories of recovery. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 544 (D.N.J. 2004). Likewise, dismissal of Plaintiffs' unjust enrichment claim would be premature even if Defendants could establish the existence of an adequate remedy at law because Plaintiffs may plead alternate, inconsistent theories. Other than New York (in which the law is unsettled), the applicable state law is consistent with this analysis.

In California,[29] the California Court of Appeals declined to dismiss an equitable claim as legally insufficient when the plaintiffs also pled an inconsistent legal claim, explaining that "the modern practice allows that party to plead in the alternative and make inconsistent allegations." *Newport Harbor Ventures, LLC v. Morris Cerullo World Evangelism*, 6 Cal. App. 5th 1207, 1224 (Cal. Ct. App. 2016), *aff'd*, 4 Cal.5th 637 (Cal. 2018). The Ninth Circuit has also held that unjust enrichment may be pursued in the alternative as a "standalone cause of action." *Bruton v. Gerber Prods. Co.*, 703 F. App'x 468, 470 (9th Cir. 2017). Thus, at the motion to dismiss stage, the plaintiffs did "not have to elect" between the equitable and legal remedies. *Id.*

In Indiana, while plaintiffs cannot **recover** for unjust enrichment "where there exists an adequate remedy at law," they are free to **plead** unjust enrichment along with legal claims at the outset and subsequently make an election of remedies. *See State ex rel. Zoeller v. Pastrick*, 696 F. Supp. 3d 970, 999 n. 7 (N.D. Ind. 2010) (finding no issue where the complaint included an unjust enrichment claim but the plaintiffs "elected the legal remedies available … in lieu of an

[29] Defendants cite two unpublished federal cases from California in which unjust enrichment claims were dismissed at the pleadings stage because of the existence of an adequate remedy at law. *See Phillips v. Ford Motor Co.*, 2015, WL 4111448, at *16 (N.D. Cal. July 7, 2015); *In re Ford Tailgate Litig.*, 2014 WL 1007066, at *5 (N.D. Cal. Mar. 12, 2014), *order corrected on denial of reconsideration*, 2014 WL 12649204 (N.D. Cal. Apr. 15, 2014). However, these cases are not binding and the conclusion that "a claim in question may be dismissed because the plaintiff has an adequate remedy at law" is "simply wrong." RESTATEMENT (3D) OF RESTITUTION AND UNJUST ENRICHMENT § 4 (2011). Rather than relying on nonbinding, unpublished federal case law, the Court should instead turn to California state courts' interpretation of their own common law. In any event, these decisions predate *Bruton*, and are overruled to the extent they conflict with *Bruton*.

equitable remedy under a theory of unjust enrichment."). "[A] party is not required to adopt a theory of the case at the outset," and may plead inconsistent theories "whether based on legal or equitable grounds." *Wood v. Walden*, 899 N.E.2d 728, 732 (In. Ct. App. 2009) (citations and quotations omitted).

In New Jersey, like Indiana, a plaintiff cannot **recover** for unjust enrichment in addition to legal claims, *Duffy v. Charles Schwab & Co., Inc.*, 123 F. Supp. 2d 802, 814–15 (D. N.J. 2000) (granting summary judgment on an unjust enrichment claim due to the existence of an adequate remedy at law, without addressing propriety of dismissing unjust enrichment claims at the pleading stage), but "may plead alternative and inconsistent legal causes of action arising out of the same facts." *Caputo v. Nice-Pak Prods., Inc.*, 693 A.2d 494, 497 (N.J. Super. Ct. 1997). For example, in *Caputo*, the plaintiff pled alternative and inconsistent theories of unjust enrichment, an equitable theory, and breach of contract, a legal theory. *Id.* The court held that the plaintiff "need not choose which one will go to the jury, as long as there is sufficient evidence as to both," and that it "is only recovery under inconsistent theories that is not permitted." *Id.* *Caputo* demonstrates that while, restitution for unjust enrichment is unavailable in the face of an adequate remedy at law at the *recovery stage*, it may still be plead as an alternative cause of action at the *pleading stage*.

Finally, in New York, state and federal courts reached different conclusions. For example, the federal district court dismissed an unjust enrichment claim due to the existence of an adequate legal remedy. *Clougher v. Home Depot U.S.A., Inc.*,696 F. Supp. 2d 285, 295 (E.D.N.Y. 2009). More recently, the New York Appellate Division held that a motion to dismiss an unjust enrichment claim was properly denied because the plaintiffs were permitted to plead unjust enrichment as an alternative basis for relief. *Art &F Fashion Grp. Corp. v. Cyclops Prod.,*

Inc., 120 A.D.3d 436, 439 (N.Y. App. Div. 1st Dep't 2014). The decision of the New York state court, interpreting its own law, should be given more weight; further, it is more consistent with this Court's interpretation of the alternate pleading rules. *See Torsiello*, 955 F. Supp. 2d at 312 n.6.

This Court, and the applicable state courts, recognize that alternative claims—whether legal or equitable—can be pled together such that dismissal for the mere reason that a legal remedy exists is premature. Accordingly, even if Defendants can establish the existence of an adequate legal remedy, dismissal of Plaintiffs' unjust enrichment claims at this stage is premature.

C. Plaintiffs Alleged a Sufficiently Direct Relationship with Defendants

The Manufacturer Defendants contend that Plaintiffs' unjust enrichment claims arising under New Jersey and New York law should be dismissed because Plaintiffs failed to allege a direct relationship with the Manufacturer Defendants. However, Plaintiffs had a sufficiently direct relationship with the Manufacturer Defendants based on the highly regulated relationship between pharmaceutical manufacturers and consumers characterized by an integrated supply chain and obligations related to the chain of commerce.

1. New Jersey

In New Jersey, unjust enrichment claims require that a "direct relationship existed between the parties which would create a reasonable expectation of benefit." *Fasching v. Kallinger*, 510 A.2d 694, 699-700 (N.J. App. Div. 1986); *see also Castro v. NYT Telev.*, 851 A.2d 88, 99 (N.J. App. Div. 2004) (holding that there was no direct relationship from which the plaintiff could have reasonably expected a benefit where a member of the public who attended a public taping of a television show claimed to expect payment for their participation). The

Manufacturer Defendants rely on a federal case involving flea products for the proposition that "[w]hen consumers purchase a product from a third party, they confer a benefit on that third party, not the manufacturer." *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 710 (D.N.J. 2011) (cited in Manufacturer MTD at 83).[30] But *Arlandson* takes the direct relationship line of reasoning further than New Jersey courts, applying their own common law, have done And *Arlandson* is distinguishable because the relationship between flea control manufacturers and customers differs substantially from the highly integrated and regulated relationships between manufacturers and end consumers in the pharmaceutical context.

In *Arlandson*, consumers sued the manufacturer of flea control products sold for use on animals. *Id.* at 695-96. The court did not describe, and there is no indication of, any integrated, highly regulated relationship between manufacturers, retailers, and end consumers of flea control products. *See generally id.* Here, the Manufacturer Defendants are subject to cGMPs to ensure that the drugs ultimately purchased by consumers meet safety standards and are prohibited from introducing into interstate commerce any adulterated or misbranded drug, that is, any drug not manufactured in compliance with cGMPs. FAC ¶¶ 142–47 (citing 21 U.S.C. §§ 331, 351(a)(2)(B)). In addition, the Manufacturer Defendants are one part of an interconnected supply chain and reimbursement system, designed to allow all entities in the supply chain to profit from the end consumer's purchase and reimbursement. FAC ¶¶ 79, 84. Thus, in the pharmaceutical context, the relationship between manufacturers and end consumers is a highly regulated, integrated relationship in which manufacturers have obligations throughout the process and are more involved in profiting from the end consumer's purchase than the situation

[30] To the extent the Retail Pharmacy Defendants adopt the Manufacturer Defendants arguments, *Arlandson* supports the existence of a direct relationship between the Retail Pharmacy Defendants and Plaintiffs since the Retail Pharmacy Defendants dispensed the MCDs directly to Plaintiffs. FAC ¶ 51.

in *Arlandson* in which the manufacturer sold a product to a retailer and was done. Pharmaceutical manufacturers **do** have direct relationships with end consumers as a result of the highly regulated, integrated system of drug manufacture and purchase. Looking to New Jersey law, as expressed by New Jersey courts, the "direct relationship" requirement of an unjust enrichment claim comes down to a "reasonable expectation of benefit." *Fasching*, 510 A.2d 699-700. In the highly regulated relationship between a pharmaceutical manufacturer and end consumer, the end consumer has a reasonable expectation of benefit because the relationship is characterized by obligations on the part of the manufacturer that relate directly to the chain of commerce. FAC ¶¶ 142–47 (citing 21 U.S.C. §§ 331, 351(a)(2)(B)). Plaintiffs have therefore established a sufficiently "direct relationship" between themselves and Defendants under New Jersey law.

2. New York

In New York, "privity is not required for an unjust enrichment claim" but "a claim will not be supported if the connection between the parties is too attenuated." *Crescimanni v. Trovato*, 162 A.D.3d 849, 851 (N.Y. App. Div. 2d Dep't 2018) (internal quotations omitted). The relationship between the parties for an unjust enrichment claim "must be one that could have caused reliance or inducement." *Id.* For example, in *Georgia Malone & Co., Inc. v. Rieder*, the court held that there was a sufficiently direct relationship between a real estate brokerage and the officers of a real estate consulting firm that received information by assuring the brokerage of its intent to complete a transaction that they ultimately terminated. 86 A.D.3d 406, 497-98 (N.Y. App. Div. 1st Dep't 2011). The relationship between the brokerage and the officers of the consulting firm "could have caused reliance or inducement," the court reasoned." *Id.* at 498.

Here, the relationship between Plaintiffs and Defendants could have caused reliance or inducement. *Crescimanni*, 162 A.D.3d at 851. Defendants contend the relationship is too

attenuated, citing *Sperry v. Crompton Corp.*, in which the manufacturer of chemicals used in the manufacture of rubber for tires and the purchaser of the tires was too attenuated for the purchaser to maintain an unjust enrichment claim. 863 N.E.2d 1012, 1018 (N.Y. 2007). However, Defendants' attempted comparison ignores the operative facts of that case. There, the defendant manufacturer made a chemical that was used in rubber that in turn was used to make tires; there was no indication that the manufacturer even knew the chemical would be used in tires or had any involvement or obligations in the process beyond selling the chemical to the rubber manufacturer. *See* 863 N.E.2d at 1018. Here, the Manufacturer Defendants were involved in the manufacture and distribution of MCDs, including production of API and manufacture of finished drug product but, throughout the process, were subject to cGMPs and the prohibition on introducing adulterated drug products into the stream of commerce. FAC ¶¶ 142–47 (citing 21 U.S.C. §§ 331, 351(a)(2)(B)). In addition, they were part of an integrated supply chain with the retailers. FAC ¶¶ 79, 84. Thus, unlike in *Sperry*, the relationship between the Manufacturer Defendants and Plaintiffs arose out of a highly regulated, integrated context in which the Manufacturer Defendants were subject to obligations involving the chain of commerce. This highly regulated, integrated relationship was exactly the type that "could have caused reliance or inducement." *Crescimanni*, 162 A.D.3d at 851. Plaintiffs therefore had a sufficiently direct, rather than an attenuated, relationship with Defendants under New York law.

D. Disgorgement is Appropriate Because Plaintiffs Pled Facts Showing that Defendants Were "Conscious Wrongdoers"

The Retail Pharmacy Defendants argue that Plaintiffs' requested remedy of disgorgement is inappropriate because disgorgement is only available against "conscious wrongdoers." Pharmacy MTD at 50. A "conscious wrongdoer" is "a defendant who is enriched by misconduct and who acts (a) with knowledge of the underlying wrong to the claimant, or (b) despite a known

risk that the conduct in question violates the rights of the claimant." RESTATEMENT (3D) OF RESTITUTION AND UNJUST ENRICHMENT § 51(3) (2011). Plaintiffs specifically plead that Defendants were "unjustly enriched through the sale of these knowingly adulterated and/or misbranded drugs." FAC ¶ 11; *see also id.* ¶¶ 7, 257, 270-71. This allegation is sufficient to establish that the Retail Pharmacy Defendants, who sold the MCDs to Plaintiffs acted "with knowledge of the underlying wrong," as necessary to establish that they were conscious wrongdoers underf the Restatement, or at a minimum that they knew of the risk to Plaintiffs. *See* RESTATEMENT (3D) OF RESTITUTION AND UNJUST ENRICHMENT § 51 (3) (2011). At the pleadings stage, Plaintiffs need not prove that they are entitled to the remedies they have requested, but only to plead sufficient facts to show that the availability of the remedy is plausible on its face. Plaintiffs have done so.

XII. THE MANUFACTURER DEFENDANTS' PERSONAL JURISDICTION ARGUMENTS LACK MERIT

The Manufacturer Defendants' argument that the Court lacks personal jurisdiction over the non-U.S. Defendants ("Foreign Defendants") ignores various procedural impediments to that defense. The argument that the Court should dismiss the FAC for improper service ignores that Plaintiffs have properly served the Foreign Defendants and that, in any case, the time limits in Fed. R. Civ. P. 4(m) (which the Manufacturer Defendants implicitly apply) do not apply to a foreign defendant. The Manufacturer Defendants are also mistaken that personal jurisdiction is not adequately established for at least two of the Foreign Defendants on grounds of alter ego and agency. They also overlook that any personal jurisdiction defense as to non-resident class members' claims is premature. Finally, Plaintiffs have shown that jurisdictional discovery would be warranted here.

A. Plaintiffs Properly Served The Foreign Defendants

The Manufacturer Defendants first argue that Plaintiffs have improperly served the Non-U.S. Defendants (Teva Pharmaceutical Industries Ltd., Emcure Ltd., Alkem Laboratories, Ltd., and Aurobindo Pharma Ltd.) or have not served the "operative" complaint on them. Manufacturer MTD at 64-65. That contention ignores that service has been properly effectuated. First, Plaintiffs properly served Teva Pharmaceuticals Industries Ltd in Israel on September 2, 2020. *See* ECF No. 91. Under Fed. R. Civ. P. 12(a)(1)(A)(i), Teva Pharmaceutical Industries Ltd. thus had until September 23, 2020 to file an answer, but failed to do so. Accordingly, because Teva has been in default since September 23, 2020, and "no entry of default by the clerk is required," *Allstate Ins. Co. v. Yadgarov*, 2014 WL 860019, at *6 (E.D.N.Y. Mar. 5, 2014) (citing cases), it has been properly served under the federal rules. *See* Fed. R. Civ. P. 5(a)(2) (service of pleading not required on defaulting party where no new claim for relief is pleaded); *see also Auto. Rentals, Inc. v. Bama Com. Leasing LLC*, 2018 WL 3159852, at *1 n.2 (D.N.J. Mar. 9, 2018).

Second, Foreign Defendants Emcure, Alkem, and Aurobindo Ltd. likewise have been properly served. They were served with the consolidated class action complaint (ECF No. 58).[31]

[31] The Manufacturing Defendants argue that Emcure, Alkem, and Aurobindo Ltd. have not been properly served under the Hague Convention. They contend that, although they received certain packages accompanied by a request for service required by the Hague Convention, "none of the forms contain a completed Certificate/Attestation page completed by the applicable Central Authority … also required by the Hague Convention." Manufacturer MTD at 65 n.20. The Court should reject this interpretation and hold these Defendants were properly served. Courts have recognized that "[t]he Hague Service Convention contemplates such a situation and does not permit a foreign sovereign to feign non-service by its own failure to complete and return the required certificate." *Crystallex Int'l Corp. v. PDV Holding Inc.*, 2019 WL 6785504, at *11 (D. Del. Dec. 12, 2019) ("For example, the first paragraph of Article 15 of the Hague Service Convention provides that a default judgment may be entered where 'the document was **actually delivered to the defendant** or to his residence by another method provided for by this Convention.' Hague Service Convention art. 15 . . . Pursuant to this first paragraph of Article 15, the Court finds (based on the undisputed evidence) that Saint-Gobain has served the Republic. By 'actually deliver[ing] to the defendant,' *i.e.*, the Republic, by serving the appropriate documents directly to the Central Authority designated by the Republic of Venezuela, Saint-

As with Teva, once these Foreign Defendants were properly served with that complaint (ECF No. 58), they had 21 days to file an answer under Fed. R. Civ. P. 12(a)(1)(A)(i). *See also SEC v. Hilsenrath*, 2005 WL 8156506, at *1 (N.D. Cal June 24, 2005) (noting that defendant's response to complaint was due 21 days from date of service of complaint, not from date on which Central Authority issued formal Hague certificate). These Foreign Defendants, however, did not file an answer and thus defaulted. *See Allstate Ins. Co.*, 2014 WL 860019, at *6. As with Teva Pharmaceutical Industries Ltd., under Rule 5(a)(2), no service of the amended complaint (ECF No. 58) is required upon them, *see Auto. Rentals, Inc.*, 2018 WL 3159852, at *1 n.2, and they should thus be considered properly served.

Third, even assuming *arguendo* that Emcure, Alkem, and Aurobindo Ltd were not effectively served with the prior, consolidated class action complaint, as set forth in the accompanying Declaration of David DaPonte ¶¶ 3-8, these Defendants have been properly served with the amended complaint (FAC).

Fourth, in any event, the Foreign Defendants could not yet be considered not properly served under the applicable law. Plaintiffs filed the FAC on June 21, 2021, and the instant motion to dismiss raising this argument was filed only 45 days later, on August 5, 2021. The Manufacturer Defendants are notably silent, however, as to what deadline applies to Plaintiffs' service of the FAC on the Foreign Defendants. Although Federal Rule of Civil Procedure 4(m) provides that service must occur within 90 days after a complaint is filed, the Rule is clear that

---

Gobain served the Republic, notwithstanding the Republic's failure to provide Saint-Gobain a certificate.") (footnotes omitted; emphasis in original); *see also Box v. Dallas Mexican Consulate Gen.*, 487 F. App'x 880, 886 (5th Cir. 2012); *Saint-Gobain Performance Plastics Eur. v. Bolivarian Republic of Venezuela*, 2021 WL 326079, at *8-10 (D.D.C. Feb. 1, 2021); *Koch Mins. Sarl v. Bolivarian Republic of Venezuela*, 514 F. Supp. 3d 20, 33-34 (D.D.C. 2020); *Sikhs for Just. v. Nath*, 893 F. Supp. 2d 598, 627 (S.D.N.Y. 2012).

that timeframe does not apply to service in a foreign country under Fed. R. Civ. P. 4(f).[32] And even if the 90-day rule did apply, it had not run when the Manufacturer Defendants moved to dismiss. Thus, even if relevant, the Manufacturing Defendants' argument that Plaintiffs have blown a deadline for service of the complaint on the Foreign Defendants should be rejected for these reasons alone.[33]

Rather than any specific time limit on service applying here, "[s]ervice on a defendant in a foreign country is more appropriately subject to a 'flexible due diligence standard.'" *Idingo LLC v. Cohen*, 2017 WL 59204, at *3 (D.N.J. Jan. 5, 2017) (quoting *In re Bulk [Extruded] Graphite Prod. Antitrust Litig.*, 2006 WL 1084093, at *3 (D.N.J. Apr. 24, 2006)). "District Courts in this Circuit have previously granted Plaintiffs multiple months to serve Defendants in a foreign country under the Hague Convention." *Id*. (citing cases). As such, Plaintiffs have not "acted in bad faith or have failed to act diligently such that a dismissal of Plaintiffs' claims is

[32] *See Plumbers' Loc. Union No. 690 Health Plan v. Apotex Corp*., 2017 WL 2242859, at *3 n.2 (E.D. Pa. May 23, 2017) ("If service of process on Teva Ltd. must occur in Israel, then Plumbers may not require an extension of time to serve Teva Ltd. because the 90-day time limit for service of process does not apply to service occurring in a foreign country.").

[33] *See* 5B CHARLES ALAN WRIGHT & ARTHUR R. MILLER, *FEDERAL PRACTICE AND PROCEDURE* § 1353 (3d ed. 2004) ("[i]t is premature to make a motion challenging service until the plaintiff's time to effect service – which is governed by Rule 4 – has expired."); *see also Pugh v. Baker*, 2019 WL 760067, at *1 n.2 (S.D. Ga. Jan. 23, 2019) ("Thus, at the time Defendant's motion was filed, Plaintiff's Complaint could not be dismissed for failure to perfect service"), *report and recommendation adopted*, 2019 WL 722590 (S.D. Ga. Feb. 20, 2019); *J.M. Smucker Co. v. Weston Firm, P.C*., 2013 WL 3713457, at *3 (N.D. Ohio July 15, 2013) ("At the time the motion [to dismiss for insufficiency of service of process] was filed, it was premature [since the timer for service of process had not run]. To the extent that the 120 time period has lapsed during the pendency of the motion, and TWF still believes that it has not been sufficiently served, TWF is free to refile the motion raising the same arguments."); *PNC Equip. Fin., LLC v. Aero Toy Store, LLC*, 2012 WL 3544660, at *3 (S.D. Ohio Aug. 16, 2012) ("When a motion to dismiss for failure of service is filed prior to the expiration of the 120 day period, as Defendants' motion was in this case, courts will generally deny that motion as premature.") (citing cases), *report and recommendation adopted*, 2012 WL 5463876 (S.D. Ohio Nov. 8, 2012); *cf. McGinnis v. Shalala*, 2 F.3d 548, 551 (5th Cir. 1993) ("Indeed, until that [90]–day period [for service] has expired, any attempt to seek dismissal on the grounds of defective service clearly would be premature.").

warranted." *Id*.; *see also Rudolph v. UT Starcom, Inc*., 2009 WL 248370, at *2-3 (N.D. Cal. Feb. 2, 2009) (Former Rule 4(m)'s 120-day service of complaint requirement does not apply to foreign defendant).[34]

As discussed above and in the Declaration of David DaPonte, Plaintiffs have made good faith efforts to effectuate service of the FAC on the Foreign Defendants. Under such circumstances, to the extent relevant here, they have satisfied the flexible due diligence standard for service on a foreign defendant. In the event the Court believes that any of the Foreign Defendants have not been properly served and that a sufficient amount of time has passed to warrant applying a deadline, in light of Plaintiffs' reasonable efforts to date, the Court should grant additional time to effect service on the Foreign Defendants. *See Canfield v. Statoil USA Onshore Properties Inc*., 2017 WL 1078184, at *13 (M.D. Pa. Mar. 22, 2017) ("Courts are also more flexible in allowing extra time for service where the plaintiff has made a good faith effort to attempt service.") (citing cases); *Invincible Ent. Partners, LLC v. EMBA Media Assocs. Ltd*., 2016 WL 10922995, at *1 (E.D. Pa. Oct. 11, 2016).

Alternatively, in the event the Court believes that proper service has not yet been effectuated on any of the Foreign Defendants, Plaintiffs respectfully request that the Court permit Plaintiffs to serve the U.S.-based counsel for the Foreign Defendants. *See Werremeyer v. Shinewide Shoes, Ltd*., No2021 WL 3291683, at *3 (D.N.J. July 31, 2021) (noting that courts have held that the proper construction of Rule 4(f)(3) vis-à-vis a foreign defendant includes service via delivery to the defendant's attorney); *Bravetti v. Liu*, 2013 WL 6501740, at

[34] The decisions cited by the Manufacturer Defendants (Manufacturer MTD at 66) are inapposite. *Mason v. Therics, Inc*., 2009 WL 44743, at *1 (D.N.J. Jan. 6, 2009), does not involve foreign defendants and thus its application of the time limitation in Rule 4(m) for service has no bearing here. And the ruling in *Eastman Kodak Co. v. Studiengesellschaft Kohle mbH*, 392 F. Supp. 1152, 1154 (D. Del. 1975), did not address any issue concerning failure to serve a non-U.S. defendant.

*3-4 (D.N.J. Dec. 11, 2013). Here, the record shows that the Foreign Defendants are on notice of the case brought against them: they are closely affiliated with one another and with a served Defendant which has been litigating this case before this Court for over a year now, they are represented by the same U.S. based counsel for purposes of the motion to dismiss, and U.S.-based counsel is in close contact with them about this case.[35] Thus, the Court should grant permission to serve the U.S.-based counsel of the Foreign Defendants, as service upon them would comport with due process.

B. Personal Jurisdiction Exists Over At Least Two Non-U.S. Defendants And Over The Non-Resident Class Members' Claims

The Manufacturer Defendants argue that the Court lacks general and specific jurisdiction over all of the Foreign Defendants. Manufacturer MTD at 67-69.

The Manufacturer Defendants argue that the Court lacks general jurisdiction over the Foreign Defendants because they are not "at home" defendants. Manufacturer MTD at 67. Specifically, these Foreign Defendants lack a principal place of business or place of incorporation in New Jersey (or anywhere else in the U.S.). *Id*. The Manufacturer Defendants also assert specific jurisdiction is lacking because Plaintiffs' causes of action do not arise out of or relate to the nonresident Defendant's contacts with New Jersey. *Id*. at 67-68.

Defendants ignore that the Plaintiffs have established a *prima facie* case of general or specific jurisdiction over at least two of the Foreign Defendants under the alter ego and agency theories.[36] Specifically, Aurobindo Pharma USA, Inc. and Teva USA Pharmaceuticals, Inc.

---

[35] *See* ECF No. 132 (Notice of Motion reflecting representation of Foreign Defendants by U.S. counsel); ECF No. 132-5 (Declaration of Brian Shanahan ¶¶ 4, 6-13, 15, 17-21; ECF No. 132-6 (Declaration of Gorla Phaneemdra Prasad); ECF No. 132-8 (Declaration of Amit Ghare); ECF No. 132-7 (Declaration of Amresh Trivedi).

[36] Under Rule 12(b)(2), "when the court does not hold an evidentiary hearing on the motion to dismiss, the plaintiff need only establish a *prima facie* case of personal jurisdiction and the

(both of which have their principal places of business in New Jersey and regularly conduct business in the U.S. on their own and through their subsidiaries, FAC ¶¶ 29, 30, 44, 45, 77) are the alter egos or agents of, respectively, Foreign Defendants Aurobindo Pharma, Ltd.[37] and Teva Pharmaceutical Industries Ltd.,[38] thus supporting the assertion of general or specific jurisdiction over these latter Foreign Defendants.

---

plaintiff is entitled to have its allegations taken as true and all factual disputes drawn in its favor." *Miller Yacht Sales, Inc. v. Smith,* 384 F.3d 93, 97 (3d Cir. 2004); *see Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 457 (3d Cir. 2003); *Femino-Ducey-Queler Orthopedic Grp. v. Blue Cross Blue Shield of Minnesot*a, 2020 WL 7640567, at *4–5 (D.N.J. Dec. 23, 2020). "'[I]n determining whether personal jurisdiction exists, the Court looks beyond the pleadings to all relevant evidence and construes all disputed facts in favor of the plaintiff.'" *Kearney v. Bayerische Motoren Werke Aktiengesellschaft*, 2021 WL 1207476, at *3 (D.N.J. Mar. 31, 2021) (internal citations omitted).

[37] *See In re Rosuvastatin Calcium Patent Litig*., 2009 WL 4800702, at *3-5 (D. Del. Dec. 11, 2009) ("Under the alter ego and agency theories, these jurisdictional contacts of Aurobindo USA may be imputed to Aurobindo [Pharma Ltd.] … Therefore, there is evidence from which a reasonable factfinder might conclude that the requirements of Delaware's long-arm statute and the Due Process Clause are satisfied. In sum, there are genuine disputes of material fact regarding whether this Court may exercise [general] personal jurisdiction over Aurobindo [Pharma, Ltd.]") (citation and footnote omitted), *report and recommendation adopted*, 2010 WL 661599 (D. Del. Feb. 19, 2010).

[38] *See City & Cnty. of San Francisco v. Purdue Pharma L.P*., 491 F. Supp. 3d 610, 635-38 (N.D. Cal. 2020) (holding that questions of fact exist requiring hearing or trial over whether Teva Ltd.'s subsidiaries—Teva USA, Cephalon, and the Actavis Generic Entities . . .—are its alter-ego, and thus whether the Court can impute these subsidiaries' contacts to Teva Ltd); *In re Nat'l Prescription Opiate Litig*., 2019 WL 3553892, at *4 (N.D. Ohio Aug. 5, 2019) (deferring until after trial decision on whether Teva USA was alter ego of Teva Ltd in light of "significant factual disputes" over plaintiffs' contentions, including that Teva Ltd. and Teva USA share same employees and corporate officers, that Teva Ltd. and Teva USA engage in same business enterprise because Teva Ltd. controls operations of its subsidiaries through integrated management team via Global Divisions, that Teva Ltd., Teva USA use the same assets, in part because they file consolidated financial results with the Securities & Exchange Commission, and that Teva Ltd. controls the daily activities of Teva USA); *cf. Teva Pharm. Indus. v. Ruiz*, 181 So. 3d 513, 517-20 (Fla. Dist. Ct. App. 2015) (holding trial court needed to hold evidentiary hearing on issue of specific jurisdiction over Teva Pharm. Industries; "[t]here was evidence that Ms. Zipp was the executive vice president and global head of quality for Teva Industries [in the United States and globally]. She testified that she handled global quality issues for all of Teva Industries both in the United States and other countries: 'I was in a global role looking at strategic activities across all Teva facilities related to quality matters[].' This would suggest that Teva Industries had a hand in the day-to-day operation and policy decisions of its subsidiaries"); *id*. at 520-21

C. Dismissal On Personal Jurisdiction Grounds Of Claims Of Non-Resident Class Members Is Premature

For non-resident class members, the Court should decline to dismiss their claims on personal jurisdiction grounds because it would be premature. Courts have held that the claims of non-resident class members should not be resolved at the motion to dismiss stage but at the class certification stage.[39] Moreover, any "dismissal of [named Plaintiffs'] claims [on personal jurisdiction grounds] does not preclude [them] from recovering as class members, if a class is certified and if those Plaintiffs qualify as members." *Lee v. Branch Banking & Tr. Co*., 2018 WL 5633995, at *4 (S.D. Fla. Oct. 31, 2018) (citation omitted); *see also Hawkins v. Well Path, LLC*, 2020 WL 4287447, at *6 (S.D.N.Y. July 27, 2020) ("[T]he Court concludes personal jurisdiction over defendant as to putative out-of-state class claims would be best assessed at the class certification stage of the proceedings, not at the motion to dismiss stage.").

D. Alternatively, The Court Should Grant Jurisdictional Discovery

If the Court does not reject the Manufacturer Defendants' personal jurisdiction arguments for the reasons above, it should, alternatively, grant jurisdictional discovery. "[I]f the plaintiff's

---

(evidence supported need for evidentiary hearing on whether Teva Pharm. Industries had sufficient minimum contacts with Florida to satisfy due process requirements).

[39] *See Beach Glo Tanning Studio Inc. v. Scottsdale Ins. Co*., 2021 WL 2206077, at *4 (D.N.J. May 28, 2021) ("The Court need not address at this stage the issue of personal jurisdiction over the claims of non-forum putative class members, because the parties agree that the issue is better addressed at the class certification stage."); *Back2Health Chiropractic Ctr., LLC v. Sentinel Ins. Co., Ltd*., 2021 WL 960875, at *5 (D.N.J. Mar. 15, 2021) (agreeing "it was 'more prudent' to address the issue of personal jurisdiction over the unnamed class members' claims at the class certification stage.") (citation omitted); *see also Molock v. Whole Foods Mkt. Grp., Inc*., 952 F.3d 293, 295-300 (D.C. Cir. 2020) (holding in Rule 23 class action that "[a]bsent class certification, putative class members are not parties before a court, rendering the defendant's motion [to dismiss all nonresident putative class members for lack of jurisdiction] premature"); *Mussat v. IQVIA, Inc*., 953 F.3d 441, 445-48 (7th Cir. 2020); *Gress v. Freedom Mortg. Corp*., 386 F. Supp. 3d 455, 465 (M.D. Pa. 2019); *Velazquez v. State Farm Fire & Cas. Co*., 2020 WL 1942784, at *11 (E.D. Pa. Mar. 27, 2020), *report and recommendation adopted*, 2020 WL 1939802 (E.D. Pa. Apr. 22, 2020); *Chernus v. Logitech, Inc*., 2018 WL 1981481, at *8 (D.N.J. Apr. 27, 2018).

claim is not clearly frivolous [as to the basis for personal jurisdiction], the district court should ordinarily allow discovery on jurisdiction in order to aid the plaintiff in discharging that burden." *Metcalfe v. Renaissance Marine, Inc.*, 566 F.3d 324, 336 (3d Cir. 2009). "Furthermore, … jurisdictional discovery is particularly appropriate where the defendant is a corporation." *Id*. (citation omitted).[40]

Plaintiffs have presented facts suggesting with reasonable particularity a basis for asserting personal jurisdiction, alleging that the Manufacturer Defendants and/or their subsidiaries have principal places of business in New Jersey and/or other New Jersey locations that are the alter egos of, or act as agents for, the Foreign Defendants, and that the Foreign Defendants made representations and warranties through websites. *See* FAC ¶¶ 29-30, 33-36, 39-40, 44-50, 77; *see also City & Cnty. of San Francisco*, 491 F. Supp. 3d at 635-38; *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3553892, at *4; *Teva Pharm. Indus.*, 181 So. 3d at 517-20; *Rosuvastatin Calcium Patent Litig.*, 2009 WL 4800702, at *3-5.[41]

[40] "[C]ourts are to assist the plaintiff by allowing jurisdictional discovery unless the plaintiff's claim is 'clearly frivolous' … If a plaintiff presents factual allegations that suggest 'with reasonable particularity' the possible existence of the requisite 'contacts between [the party] and the forum state' … the plaintiff's right to conduct jurisdictional discovery should be sustained." *Toys "R" Us, Inc.*, 318 F.3d at 456 (internal citations omitted).

[41] *See also Philadelphia Contribution Ship Ins. Co. v. Neoteric Sols. Inc.*, 2016 WL 791427, at *2 (D.N.J. Feb. 5, 2016) (jurisdictional discovery warranted where facts possibly indicated that foreign defendant conducted business in form through local agent), *report and recommendation*, 2016 WL 780570 (D.N.J. Feb. 24, 2016); *Thermolife Int'l, LLC v. Prosource Performance Prod.*, 2015 WL 9480023, at *5 (D.N.J. Dec. 29, 2015) (granting jurisdictional discovery where plaintiffs asserted alleged defendants conducted business in forum through websites); *News India USA, LLC v. Vibrant Media Grp., LLC*, 2013 WL 5287614, at *4 (D.N.J. Sept. 17, 2013) (granting jurisdictional discovery where allegations suggest "it is possible that Defendant has availed itself of New Jersey through its operation of this website"); *Bellator Sport Worldwide, LLC v. Zuffa, LLC*, 2011 WL 13141495, at *6 (D.N.J. May 16, 2011) (granting limited jurisdictional discovery to determine whether New Jersey residents visited defendants' websites), *report and recommendation adopted*, 2011 WL 13141663 (D.N.J. Dec. 16, 2011).

Plaintiffs have also shown that they are entitled to jurisdictional discovery with respect to the Foreign Defendants Aurobindo Pharma, Ltd. and Teva Pharmaceutical Industries Ltd., based on the alter ego or agency theory discussed above. *See Deardorff v. Cellular Sales of Knoxville, Inc.*, 2020 WL 5017522, at *7 (E.D. Pa. Aug. 25, 2020) (granting jurisdictional discovery where "Plaintiffs' evidence in the record raises at least the possibility of personal jurisdiction over CSOKI based on an alter ego theory."); *StemGenex, Inc. v. Balshi*, 2015 WL 4545867, at *3 (S.D. Cal. July 27, 2015) (same); *see also Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 781 (3d Cir. 2018) (granting jurisdictional discovery to explore alter ego theory of general jurisdiction where allegations plausibly alleged subsidiary was agent of parent or parent controlled subsidiary). As such, the Court should, at a minimum, grant jurisdictional discovery of the Foreign Defendants.

CONCLUSION

For the foregoing reasons, both the Manufacturer Defendants' Motion to Dismiss and the Retail Pharmacy Defendants' Motion to Dismiss should be denied in full.

Dated: September 20, 2021

Respectfully submitted,

CARELLA BYRNE CECCHI
OLSTEIN BRODY & AGNELLO, P.C.
By: */s/ James E. Cecchi*
James E. Cecchi, Esq.
5 Becker Farm Road
Roseland, NJ 07068
Tel: (973) 994-1700
E-mail: jcecchi@carellabyrne.com

Interim Liaison Counsel for Plaintiffs

BURSOR & FISHER, P.A.
By: */s/ Scott A. Bursor*
Scott A. Bursor, Esq. (*Pro Hac Vice*)
701 Brickell Avenue, Suite 1420
Miami, FL 33131
Tel: (305) 330-5512

E-mail: sbursor@bursor.com

HONIK LLC
By: */s/ Ruben Honik*
Ruben Honik, Esq.
1021 Kitchens Lane
Philadelphia, PA 19119
Phone (215) 327-9166
E-mail: ruben@honiklaw.com

RIVERO MESTRE LLP
By: */s/ Jorge A. Mestre*
Jorge A. Mestre, Esq. (*Pro Hac Vice*)
2525 Ponce de Leon Blvd, Suite 1000
Miami, FL 33134
Tel: (305) 445-2500
E-mail: jmestre@riveromestre.com

Interim Co-Lead Counsel for Plaintiffs